SHAREHOLDER LETTER

December 2021

Dear Poxel Shareholder,

As we are approaching the end of the year, I would like to share the significant milestones that we have achieved in 2021, which has been a pivotal year for Poxel.

Firstly, 2021 is notable for our first drug approval in June for Imeglimin, which is now launched and marketed as TWYMEEG® in Japan since mid-September. We see this approval as the result of years of hard work and dedication from our teams, together with the successful collaboration with our strategic partner, Sumitomo Dainippon Pharma. We are very proud of this achievement which increased our financial position through a EUR 13.2 million milestone payment from Sumitomo and EUR 13.5 million from the 3rd and final tranche of the IPF loan. The commercialization of TWYMEEG ® in Japan and in additional Asian countries, will continue to augment our financial foundation with associated future royalties and sales-based payments.

After Imeglimin's approval in Japan, another major step in Poxel's evolution in 2021 was the announcement of a new strategic direction with increasing focus on rare metabolic diseases. This strategic focus area represents the intersection of high unmet medical needs, pre-clinical and clinical data, opinion leader enthusiasm, significant commercial opportunity, and attractive time horizons. We believe that Poxel is well equipped to be a leader in this field given our exciting programs and our proven capabilities to execute successful clinical trials and regulatory filings. We plan to initiate the Phase 2a clinical Proof of Concept (POC) biomarker studies of PXL065 and PXL770 in X-linked adrenoleukodystrophy (ALD) in early 2022 with data expected by year end 2022.

In parallel, we remain committed to non-alcoholic steatohepatitis (NASH). The patient enrollment in PXL065 DESTINY Phase 2 trial in NASH was completed in September 2021 and we are looking forward to share with you the results, expected in Q3 2022.

With these accomplishments in mind, and several important and transformational milestones expected in 2022, I would like to thank you for your support and look forward to providing you with further updates in the coming year.

Sincerely,

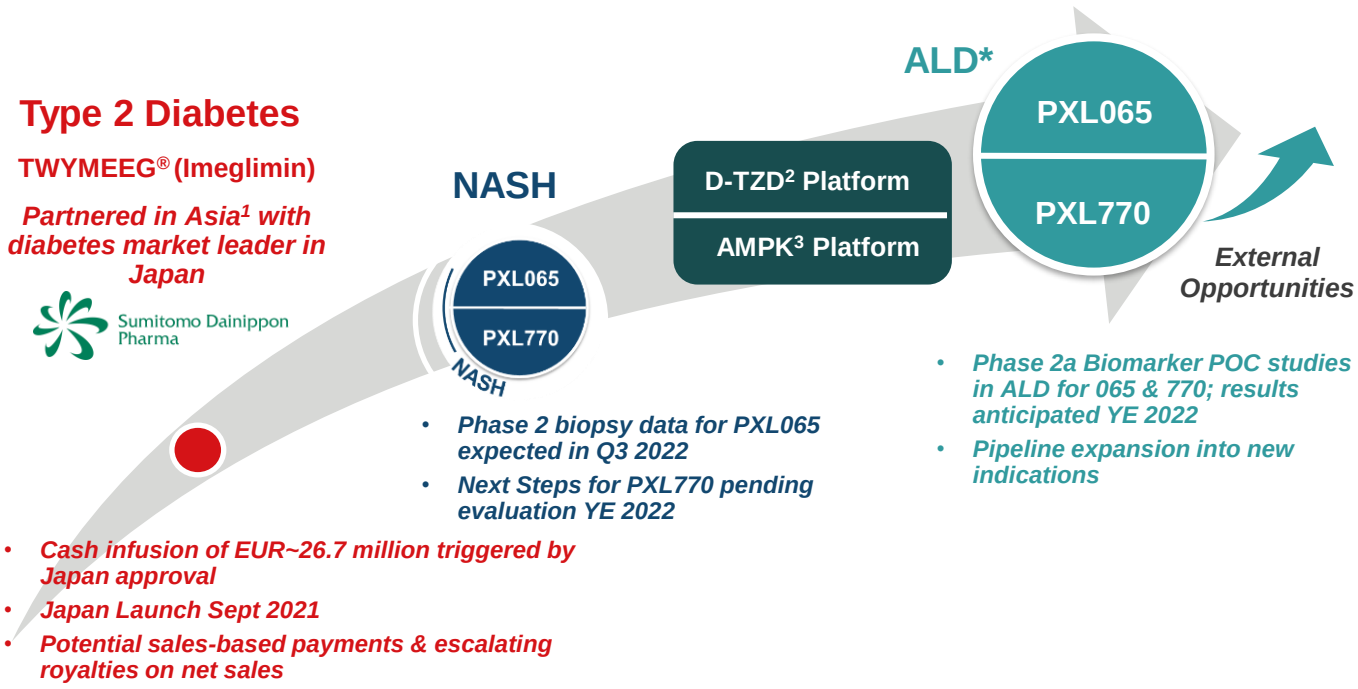
Thomas Kuhn

Chief Executive Officer

Contents

Poxel Focuses on Rare Metabolic Diseases and NASH to Drive Shareholder Value

After the successful development and approval of Imeglimin, and thanks to its 2 platforms of molecules, Poxel is well positioned to be a significant player in NASH and rare metabolic diseases, driving shareholder value.



1. Japan plus: China, South Korea, Taiwan, Indonesia, Vietnam, Thailand, Malaysia, Philippines, Singapore, Myanmar, Cambodia, Laos.
2. Deuterium-modified thiazolidinediones.
3. AMP-kinase (allosteric activators) /

* X-linked adrenoleukodystrophy (ALD).

The Company is Developing a Well-Diversified and Robust Pipeline with Mid-to-Late-Stage Programs with a Focus on Rare Metabolic Diseases and NASH

	Indication	MOA	Preclinical / Phase 1 / Phase 2 / Phase 3	Approved / Marketed	Partner/ Rights	Upcoming Milestones
Type 2 Diabetes						
TWYMEEG® Japan / Asia	Type 2 Diabetes (T2D)	MRC Modulator			Sumitomo Dainippon Pharma	• TWYMEEG® approved for T2D in Japan in June 2021 • Product launched in September 2021
Imeglimin US / EU / Other	TD2 with CKD stages 3b/4	MRC Modulator			poxel	• Exploring options to move the program forward into Phase 3
NASH						
PXL065	NASH	Non-Genomic TZD			poxel	• Phase 2 results expected Q3 2022 • 505(b)(2) pathway
PXL770	NASH	AMPK Activator			poxel	• Successful Phase 2a Study • Evaluate next steps by year end 2022
Rare Metabolic Indications						
PXL770	ALD	APMK Activator			poxel	• Initiate Phase 2a Q1 2022
PXL065	ALD	Non-Genomic TZD			poxel	• Initiate Phase 2a Q1 2022
Next-Gen APMK	Not Disclosed	AMPK Activator			poxel	• Complete PC studies in 2021
Next-Gen D-TZD	Not Disclosed	Non-Genomic TZD			poxel	• Select lead candidate(s)

TWYMEEG® (Imeglimin)

2021 marks the first approval of Poxel lead compound, Imeglimin

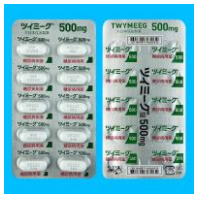
Keys milestones for TWYMEEG®

Regulatory approval
June 2021

Commercial launch
September 2021

TWYMEEG® (International Nonproprietary Name (INN): Imeglimin hydrochloride**) approval in June 2021 in Japan** for the treatment of type 2 diabetes was supported by numerous preclinical and clinical studies, including the Phase 3 TIMES (Trials of IMeglimin for Efficacy and Safety) program managed jointly by Poxel and Sumitomo Dainippon Pharma. Japan is the first country in the world to approve Imeglimin.

Sumitomo Dainippon Pharma, the diabetes market leader in Japan, **launched TWYMEEG® in September 2021**.



Partnership in Asia with diabetes market leader, Sumitomo Dainippon Pharma

Sumitomo Dainippon Pharma

Poxel entered into a **strategic partnership with Sumitomo Dainippon Pharma in October 2017** for the development and the commercialization of TWYMEEG® in Japan, China, South Korea, Taiwan and nine other Southeast Asian countries (Indonesia, Vietnam, Thailand, Malaysia, the Philippines, Singapore, Myanmar, Cambodia and Laos).

Terms of the partnership and payments with Sumitomo Dainippon Pharma

- Milestone payment for TWYMEEG®'s approval in Japan of JPY 1.75 billion (approximately EUR 13.2 million, USD 15.8 million)[1] paid by Sumitomo Dainippon Pharma to Poxel in July 2021. The approval is supported by the Phase 3 TIMES program managed jointly with Sumitomo Dainippon Pharma.
- As part of the license agreement where Sumitomo Dainippon Pharma solely manages the commercialization, Poxel expects to receive escalating royalties on net sales and sales-based payments.

[1]Converted at the exchange rates at date of approval (June 23, 2021).

Imeglimin's potential market in Asia

Japan

According to *Decision Resources*, **Japan is the second largest diabetes market worldwide, behind the United States**, with a compounded annual growth rate of more than 18% between 2008 and 2012 and could grow by more than 20% by 2023. It is estimated that there are currently **over 10 million diabetic patients in Japan and sales in this market exceeded $4 billion in 2020**. The Japanese diabetes market has specific pricing and reimbursement characteristics that could allow a rapid market uptake for new innovative products.

China

According to IQVIA, there were **approximately 112 million adults diagnosed with type 2 diabetes in China in 2017** and the prevalence is expected to grow by approximately 1.7% per year. In 2017, sales of type 2 diabetes therapies were approximately $3 billion, with oral drug sales representing approximately 50% of that total. China represents a growing commercial opportunity for Imeglimin, if approved. We believe that Imeglimin has the potential to target the estimated 29 million patient population in China being treated with Western drugs, as well as the sizeable patient population with co-existing chronic kidney disease (CKD).

Other: South Korea, Taiwan, Indonesia, Vietnam, Thailand, Malaysia, the Philippines, Singapore, Myanmar, Cambodia and Laos.

Imeglimin in the US and Europe

USA and Europe

Approximately 2.4 million adults in the United States have type 2 diabetes and chronic kidney disease (CKD) stages 3b/4, according to the Centers for Disease Control and Prevention, and these patients have increased cardiovascular, or CV risk and challenging glucose management requirements.

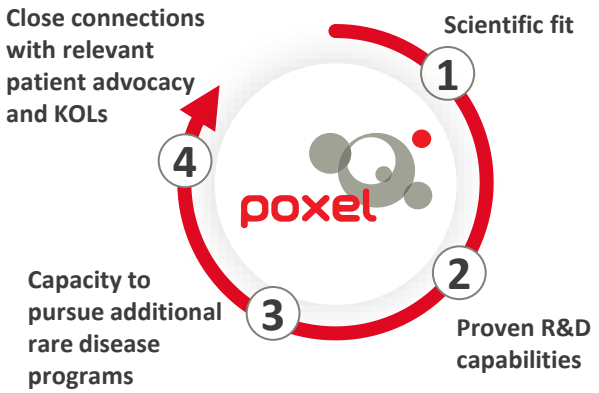
Strategy

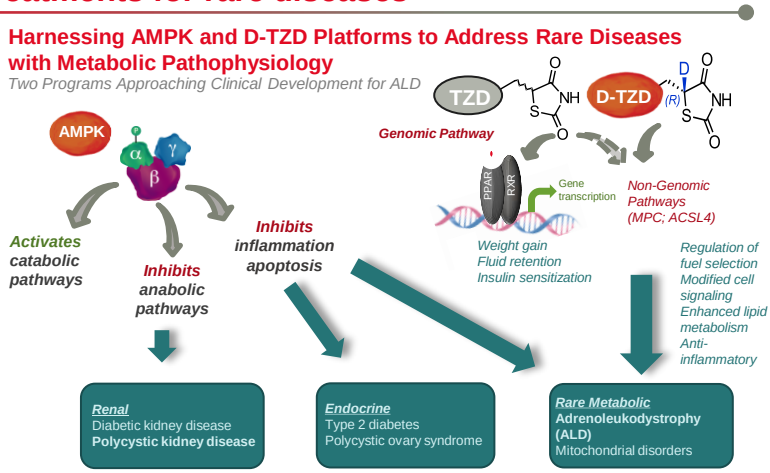
For the United States, Europe and all other countries not covered by the Sumitomo Dainippon Pharma agreement, Poxel is considering various options to advance Imeglimin in those countries. Its previous partner, Metavant, a subsidiary of Roivant, had been in discussions with the U.S. Food and Drug Administration, which has provided a potential plan forward for Imeglimin in a Phase 3 which would evaluate type 2 diabetes patients with chronic kidney disease (CKD) stages 3b/4. Poxel is exploring options to move the program forward into Phase 3 in these regions.

New strategic direction with increasing focus on rare metabolic diseases

After the approval of our first product in Japan, the product launch by our partner SDP opens a new chapter for Poxel to drive shareholder value. With additional funding from TWYMEEG®, we are investing these funds to accelerate and expand our clinical pipeline of rare metabolic disease programs.

Poxel unique attributes for developing treatments for rare diseases



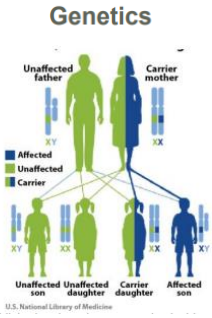


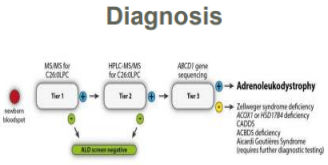
Focus on Adrenoleukodystrophy (ALD)

X-linked adrenoleukodystrophy (ALD) is an **orphan neurometabolic disease**. It is caused by the mutation of a single gene (named ABCD1). This gene is responsible for the break down of specific forms of fatty acids (called VLCFAs), which provides the body with energy. Because this particular gene is defective in ALD patient, fatty acids build up in blood, certain tissues and organs, specifically in the brain, which leads to multiple progressive defects. ALD is the most common leukodystrophy with a prevalence similar to hemophilia – up to 1/10,000.

Forms of this disease include cerebral ALD (C-ALD) and adrenomyeloneuropathy (AMN) which is the most common form – typically occurring in adolescence through adulthood. AMN results in progressive stiffness and weakness in the legs, impaired gait and balance, incontinence, and loss of sensation. All men with the genetic mutations are more severely affected and many women also present with features of AMN with a later onset. It can lead to severe neurologic deficits and death.

There are **no approved medicines for ALD** (other than glucocorticoid supplements for associated adrenal insufficiency). C-ALD when first detected in early childhood, can be treated with hematopoietic stem cell transplantation, but it is currently limited to early stage of CALD and this procedure is at risk of severe adverse reactions.





ALD, a high value opportunity

Blockbuster market opportunity

- **Prevalence :** US 20,000-29,000; Global 444,000 – 644,000
- **Premium pricing** supported by prior orphan drug approvals
- **Poxel ability to commercialize on its own** which would allow to capture **greater economics**
- **Low competition**

Preclinical & Clinical Profile

- **Established safety profiles** of PXL065 and PXL770 mitigate risk & may reduce clinical development timelines
- **Significant impact on key biomarkers** (VLCFA, neurofilament light chain) following data from ALD preclinical models for PXL065 and PXL770
- Poxel **equipment** given **exciting programs and capabilities**
- **Potential for accelerated approval** based upon biomarkers

Community engagement

- **Established relationships** with Key Opinion Leaders
- **Collaborations** with important patient advocacy groups

New strategic direction with increasing focus on rare metabolic diseases

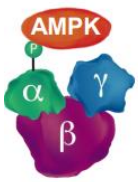
Two First-in-Class Advanced Lead Molecules in ALD

PXL065

- Deuterium stabilized *R*-stereoisomer of pioglitazone[1]
- Preclinical:
  - no (PPARγ –driven) weight gain/fluid retention
  - metabolic and anti-inflammatory efficacy
- Clinical
  - completed Phase 1
  - confirmed selective *R*-pio exposure
  - good safety profile in >130 human exposures (Phase 1 plus ongoing Destiny-1 NASH trial)
  - Pioglitazone efficacy achieved in ABCD1 null mice
  - PXL065 is active in ALD/AMN patient-derived cells and in ABCD1-null mice
- Composition of matter IP
- 505(b)(2) regulatory path; open IND in ALD/AMN

PXL770

- Proprietary direct allosteric AMPK activator[2]
- Preclinical:
  - Metabolic, anti-inflammatory, cytoprotective efficacy in NASH, diabetes, kidney, CV models
- Clinical
  - orally bioavailable; once daily PK profile
  - human target engagement and efficacy demonstrated (diabetes and NAFLD)
  - well tolerated with favorable safety profile>200 human exposures up to12 weeks
  - AMPK activation with metformin elevates ABCD2 levels in patient cell lines and ABCD1-null mice
  - PXL770 is active in ALD/AMN patient-derived cells and in ABCD1-null mice
- Composition of matter IP



[1]approved Type 2 diabetes therapy (Actos); Jacques V et al. Hep Comm 2021; implicated in ALD - Brain 2013;136:2432-43
[2]Gluais-Dagorn et al. Hep Comm 2021; implicated in ALD – Weidling I J Neurochem 2016

Support from the ALD community

Ben Lenail

Co-founder and Board member of ALD Connect

"My story with ALD starts around age 40. I went through a two-year diagnostic and was finally diagnosed in 2011. I started a foundation, ALD Connect, which is now the premier patient-driven research collective in the US. It has been in operation for eight years. We are coming out of years of better understanding the disease, but we have no treatments to help with our symptoms, to give us hope for a disease-modifying therapy or even for a cure. And so, you have the patient communities hungry, mobilized, and extremely ready to try treatments in this window of opportunity that we have today." – **Poxel business update call, 12th July 2021**

Prof. Marc Engelen, MD, PhD

Member of Poxel SAB on ALD

"Adrenoleukodystrophy is a rare disease that is actually not so rare. There are tens of thousands of patients in Europe and the US, and hundreds of thousands worldwide. It is a monogenic neurodegenerative disorder that is characterized by defective very long chain fatty acid degradation. Even though it is an X-linked disease, it causes symptoms in men and women with differences in symptomatology." - **Poxel business update call, 12th July 2021**

Upcoming clinical studies for rare metabolic diseases

Based on all the preclinical and clinical data we have for both platform leads, we now plan to initiate two parallel Phase 2a biomarker-driven POC studies; one with PXL065 and one with PXL770. The study design was developed with substantial input from several disease experts in the US and Europe. Each trial will enroll approximately 12 adult male patients per dose group with the most common subtype of ALD, AMN. Following a run-in period, patients will be treated for 12 weeks with a single oral daily dose of either molecule. Readouts will include PK, safety and measurements at several time points – of key disease biomarkers – VLCFA and neurofilament light chain – both of which are validated as disease-associated. Additional exploratory biomarkers will also be assessed.

Early 2022
Beginning of trials

Late 2022
Data analysis and selection of the preferred molecule

Next steps
Further discussions with experts and patients
Finalization of Phase 3 plan with regulatory agencies
NDA/MAA filing

NASH PORTFOLIO - PXL770 and PXL065

Reaffirming commitment in NASH with PXL770 and PXL065

- **PXL065**

PXL065 is a novel, proprietary deuterium-stabilized R-pioglitazone. Although pioglitazone is not approved by the FDA for the treatment of NASH, it is the most extensively studied drug for NASH and has demonstrated "resolution of NASH without worsening of fibrosis" in a Phase 4 trial1. Pioglitazone is the only drug recommended for biopsy-proven NASH patients by the Practice Guidelines published by the American Association for the Study of Liver Diseases (AASLD) and the European Association for the Study of the Liver (EASL)2. Pioglitazone's off-label use for NASH, however, has been limited due to the PPARγ-related side effects, which include weight gain, bone fractures and fluid retention.

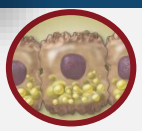
Pioglitazone is a 1:1 mixture of two mirror-image compounds (R- and S-stereoisomers) that interconvert *in vivo*. Using deuterium, we stabilized each stereoisomer and characterized their different pharmacological properties. *In vitro* studies have shown that PXL065 targets the non-genomic pathways of thiazolidinediones and in particular inhibits the mitochondrial pyruvate transporter (MPC). In preclinical animal models, PXL065 exhibits the anti-inflammatory and NASH activity associated with pioglitazone with little or no weight gain or fluid retention, side effects which are associated with the S-stereoisomer. Based upon preclinical and Phase 1 results to date, Poxel believes that PXL065 may have a better therapeutic profile than pioglitazone for NASH.

- **PXL770**

PXL770 is a first-in-class AMPK activator. AMPK is a central regulator of multiple metabolic pathways leading to the control of lipid metabolism, glucose homeostasis and inflammation. Based on its central metabolic role, targeting AMPK offers the opportunity to pursue a wide range of indications to treat chronic metabolic diseases, including diseases that affect the liver, such as NASH.

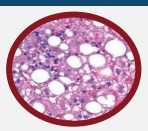
NASH value proposition

HALLMARKS OF NASH

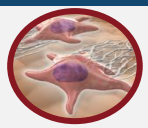


Lipid accumulation in hepatocytes
Steatosis

Immune cells (macrophages - MΦ)
Inflammation



Cellular damage-death
Ballooning



Hepatic stellate cell activation
Fibrosis

- **First-in-Class - Novel Mechanisms**
  - ability to target multiple hallmarks of NASH
- **Clinical validation**
  - positive Phase 2a results (PXL770)
  - derived from pioglitazone – proven NASH benefits (PXL065)
- **Daily oral administration**
  - combinable with other approaches
- **Innovative development approaches**
  - focus on patients with co-existing diabetes (PXL770)
  - 505(b)(2) regulatory path (PXL065)

Results from on-going PXL065 Phase 2 trial (DESTINY-1) anticipated in Q3 2022

- PXL065 is currently evaluated in the DESTINY-1 Phase II trial for the treatment of NASH and the results of this study will be used to help identify the dose(s) for a Phase III registration trial. Patient enrollment in Phase II trial was completed in September 2021 with results expected in Q3 2022.

Key inclusion criteria

- Biopsy-proven NASH patients
- Liver fat content (MRI-PDFF) ≥ 8%

Randomization 1:1:1:1

- PXL065 7.5 mg QD / 30 patients
- PXL065 15 mg QD / 30 patients
- PXL065 22.5 mg QD / 30 patients
- Placebo QD / 30 patients

Week 36

Double-blind treatment: 36 weeks

Primary Endpoint

- Relative change in liver fat content (MRI-PDFF)

Secondary Endpoints

- Liver histology: NASH resolution without worsening of fibrosis
- Liver enzymes
- Metabolic parameters
- Biomarkers, Safety, PK

POXEL IN THE MEDIA

Les Echos

LA STRATÉGIE POXEL

Première approbation de son antidiabétique au Japon

Date de création : 2009
DG : Thomas Kuhn
Effectif : 60 personnes
Secteur : biopharmacie

Léa Delpont
— Correspondante à Lyon

Onze ans après sa création et quelque 230 millions d'euros levés, Poxel obtient sa première approbation de mise sur le marché. Le Japon vient de donner son feu vert à la molécule d'Imeglimine, dotée d'un double mécanisme d'action : sur le pancréas pour la production d'insuline et sur les mitochondries pour le métabolisme du glucose. Cette autorisation, obtenue après une étude clinique de phase III concluante, déclenche un paiement d'étape de 13,3 millions par son partenaire nippon, en attendant les prochains plafonnés à 200 millions. Le groupe pharmaceutique Sumitomo Dainippon accompagne Poxel au Japon, en Chine et dans onze pays d'Asie du Sud-Est. La biotech lyonnaise percevra des redevances à deux chiffres sur les ventes, sous la marque Twymeeg déposée par Sumitomo. « *L'Imeglimine a été inventée chez Merck au milieu des années 2000* », rappelle le directeur général de Poxel, Thomas Kuhn, qui a pris la tête du spin-off créé en 2009.

Première molécule d'une nouvelle classe chimique, elle s'administre par comprimés, matin et soir. « *Elle est indiquée pour retarder le passage à l'insuline dans le traitement du diabète de type 2 – 90 % des cas – en monothérapie ou en complément d'autres traitements* », explique-t-il. Cette annonce arrive à point nommé pour la société cotée depuis 2015 sur Euronext. En novembre 2020, son partenaire américano-suisse Metavant, filiale de Roivant Sciences, a renoncé à poursuivre le développement de l'Imeglimine sur les marchés américain et européen, après avoir investi 28 millions d'euros dans les droits, achetés pour 12 millions d'actions de la biotech lyonnaise – dont il détient toujours 5 % –, et mené des études de phase I et II sur les diabétiques en insuffisance rénale.

D'abord la NASH

Poxel a récupéré les droits, les données et les brevets sans dégâts financiers. « *La stratégie de niche était bonne, nous allons poursuivre dans cette voie pour commencer* », estime Thomas Kuhn, qui cherche un nouveau partenaire pour la phase III. Avec près de 50 millions de trésorerie, Poxel veut réorienter ses efforts vers d'autres maladies métaboliques, d'abord la NASH pour laquelle il a déjà deux candidats médicaments. ■

investir

PHARMACIE-SANTÉ

Poxel L'imeglimine va être commercialisée au Japon

Ce spécialiste des traitements des maladies métaboliques, notamment le diabète de type 2 et la Nash (maladie du foie gras), a annoncé une très bonne nouvelle. Son traitement phare, l'imeglimine, un antidiabétique oral utilisant un nouveau mécanisme d'action, a été approuvé au Japon. Le partenaire de Poxel, Sumitomo, qui a pris le produit en licence pour le Japon, avait déposé le dossier d'enregistrement en 2020. Poxel va percevoir de ce dernier 13,3 millions d'euros et est éligible à 200 millions, en fonction de paliers de ventes, ainsi qu'à des royalties. Sumitomo est le premier acteur dans l'archipel sur un marché du diabète qui pèse 5 milliards de dollars et compte 10 millions de diabétiques. L'imeglimine cible 80 % des patients diabétiques au Japon, qui sont soignés par des inhibiteurs de la DPP-4. Ces traitements oraux retardent l'administration d'insuline, mais perdent de leur efficacité avec le temps. L'imeglimine, combiné à ces traitements, notamment à Equa, le produit phare de Sumitomo, améliore leur effet. Le lancement commercial va démarrer au troisième trimestre et bénéficiera d'une force de vente de 800 visiteurs médicaux qui lui seront entièrement consacrés. Sur la base d'un prix annuel de 700 $, Sumitomo devrait capter un marché entre 400 et 450 millions de dollars. « *Ce niveau de ventes pourrait être atteint dans les trois à cinq ans, alors que sept ans sont nécessaires en Europe pour arriver au pic d'activité* », indique le directeur général, Thomas Kuhn.

DU POTENTIEL

Ce succès valide la qualité de la technologie de Poxel et sa capacité à mettre un médicament sur le marché. Il devrait faciliter un accord de partenariat pour l'imeglimine en Europe et aux Etats-Unis, après le retrait, en 2020, du partenaire américain Metavant, qui avait souhaité sortir du diabète. « *Le feu vert au Japon dérisque le produit. Les données cliniques sur les 1.100 patients testés seront intégrées aux essais de phase III que devra réaliser notre futur partenaire. Des discussions sont en cours avec des acteurs du domaine du diabète ou des pathologies rénales, car nous ciblons dans ces zones géographiques très concurrentielles le segment des insuffisants rénaux, où le besoin médical est très élevé* », précise Thomas Kuhn.

Enfin, les essais de phase II se poursuivent dans la Nash pour PXL770 et PXL065. La trésorerie offre une visibilité jusqu'à 2023, hors nouveaux revenus. – **A. B.**

NOTRE CONSEIL

ACHAT SPÉCULATIF : le titre, qui a chuté de 80 % depuis mars 2020, est injustement sanctionné, alors que l'autorisation de l'imeglimine est de bon augure pour la concrétisation d'un nouveau partenariat.
Objectif : 10 € (POXEL).

CRITÈRES D'INVESTISSEMENT

COMPORTEMENT DE L'ACTION		PERFORMANCE OPÉRATIONNELLE	
PERFORMANCE DU TITRE		ÉVOLUTION DE L'ACTIVITÉ	
COURS AU 24-6-21 :	7,04 €	ÉVOL. MOYENNE (2017-2020) :	41 %
VARIATION 52 SEMAINES :	- 13,73 %	ÉVOL. 2021 :	- 20 %
2021 :	10,69 %	BNPA	
LIQUIDITÉ		ÉVOL. MOYENNE (2017-2020) :	NS
VOL. QUOT. MOYEN ÉCHANGÉ :	228.318	ÉVOL. 2021 :	NS
EXTRÊMES 52 S. :	8,37 € / 5,72 €		
CONFIANCE DANS LA SOCIÉTÉ		**INTÉRÊT BOURSIER**	
SOLIDITÉ DU BILAN		RENDEMENT	
TRÉSO. NETTE / FONDS PROPRES :	150 %	DIVIDENDE 2021 ESTIMÉ :	0
DERNIER ACTIF NET PAR ACTION :	1,04 €	RDT 2020 : NUL	RDT 2021 : NUL
PART DU CAPITAL DÉTENUE PAR		VALORISATION ESTIMÉE	
BPI :	147 %	PER 2021 :	NS
		PER 2022 :	NS

PEA-PME

BIOTECHFINANCES

POXEL : 1ER MÉDICAMENT SUR LE MARCHÉ

Douze ans après sa création, Poxel, *spin-off* de Merck Serono, obtient sa première autorisation de mise sur le marché d'un médicament. Il s'agit de sa molécule phare, l'Imeglimine, qui est à l'origine de la constitution de l'entreprise spécialisée dans les traitements de maladies métaboliques. Certes pour atteindre la ligne d'arrivée, Poxel a été accompagnée par le laboratoire japonais Sumitomo Dainippo Pharma qui détient les droits exclusifs en Asie sur cet antidiabétique depuis 2017. Cette première autorisation de mise sur le marché (AMM) a été délivrée par l'agence réglementaire japonaise, dans une indication très large : le diabète de type 2. « *Dans cette aire thérapeutique, le Japon représente le 2e marché mondial derrière les États-Unis. Avec plus de 10 millions de patients sa taille est estimée à 6-5 Mds$ par an* », indique Thomas Kuhn, le directeur général de Poxel.

« Le marché japonais estimé à 5 Mds$ est le 2e mondial dans le diabète. »

450 M$ de ventes par an

Au-delà de la réussite scientifique, l'AMM se traduit financièrement par un paiement d'étape de 13,3 M€ pour la biotech lyonnaise. Ce montant vient donc s'ajouter à un upfront de 42 M€ perçu il y a quatre ans et aux 4,1 M€ reçu l'an dernier lors du dépôt du dossier auprès de l'agence nippone. Par la suite, la biotech lyonnaise touchera un pourcentage (à deux chiffres) sur les ventes réalisées auquel s'ajouteront des milestones pouvant atteindre 200 M€ en fonction des seuils de chiffre d'affaire franchi par Sumitomo. De leur côté, les analystes financiers évaluent à 400-450 M$ par an le potentiel de ventes de l'Imeglimine au Japon. « *Le laboratoire japonais détient les droits dans 12 autres pays d'Asie et a entamé l'an dernier des discussions avec les autorités chinoises en vue d'un enregistrement. Une étude clinique supplémentaire incluant des patients chinois sera à priori nécessaire dans ce pays qui compte 120 millions de diabétiques* » commente Thomas Kuhn. « *Mais le coût du traitement générique utilisé étant relativement faible, c'est un marché de plus petite taille, environ 3 Mds$* », précise-t-il.

Partenaire en UE et aux USA

En attendant la commercialisation au Japon devrait débuter l'an prochain, Sumitomo spécialisé dans le diabète est fin prêt à lancer un nouveau médicament pour rebooster sa gamme. L'Imeglimine fonctionne en monothérapie ou en complément d'autres antidiabétiques.

Reste désormais à confirmer l'essai aux États-Unis et en Europe. Sur ces marchés Poxel est allé jusqu'au bout de la phase 2 dans une indication plus étroite, celle des patients diabétiques souffrant d'insuffisance rénale. Son partenaire industriel, Metavant, a même préparé le terrain de la phase 3 avec la FDA avant de changer d'avis et de rétrocéder les droits à Poxel fin janvier. Depuis, la biotech cherche une nouvelle collaboration pour terminer cette ultime étape clinique et réglementaire. « *Nous discutons avec plusieurs acteurs du secteur, certains spécialistes dans le diabète, d'autres dans l'insuffisance rénale, mais cela prend du temps en termes de due diligence notamment* », souligne le dirigeant. L'AMM obtenue au Japon pourrait bien accélérer le process. ■ *Anne-Laure Julien*

59,4 M€
Montant perçu à ce jour par Poxel dans le cadre de son partenariat avec Sumitomo.

2039
Les dernières dates d'expiration des brevets en vertu du contrat de licence Sumitomo sont prévues pour 2039.

2
Poxel conduit 2 programmes cliniques dans la NASH, une phase 2 avec PXL770 dont les résultats sont attendus mi-2022 et une phase 2b avec PXL065 qui débutera à la fin de l'année.

LABIOTECH.eu

Poxel's Diabetes Drug Wins Japan Nod, But Competition Remains Fierce

BY ANITA CHAKRAVERTY
02/07/2021 · 5 MINUTES

Scrip
Informa Pharma Intelligence

Poxel/Sumitomo's Novel Diabetes Therapy Imeglimin Nears Japan Market

A Phase III-Ready Partnering Opportunity

25 Mar 2021 | NEWS

by John Davis
john.davis@informa.com

Executive Summary

Poxel's potential first-in-class diabetes the
and a new partner is being sought for the E
the decade-old Merck Serono spin-out.

FIERCE Biotech

Biotech

Poxel pivots to different programs, but questions ab over imeglimin

LYON décideurs

BioPharma Media
Credible, reliable, equitable.

METABOLISM | NEW DRUGS | REGULATORY

Twymeeg: Completely New Drug for Treatment of Type 2 Diabetes Mellitus

Imeglimin is a universal anti-diabetic drug that incorporates the power of all existing glucose-lowering drugs.

france 3

UPCOMING NEWSFLOW

NASH

2022

- **DESTINY Phase 2 trial**: Results are expected in Q3 2022

DIABETES

2022

- Sales-based payments and escalating royalties on net sales
- US/Europe: exploring options to move the program forward into Phase 3

RARE METABOLIC DISEASES

2022

- Poxel plans to initiate two Phase 2a biomarker proof-of-concept clinical trials for PXL065 and PXL770 in X-linked adrenoleukodystrophy (ALD) in early 2022. Results planned for the end of 2022.

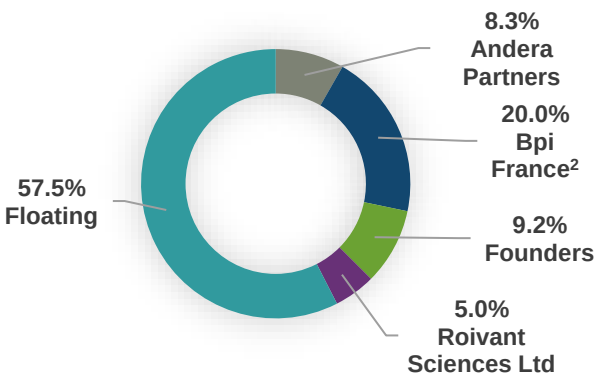
SHAREHOLDER'S NOTEBOOK

POXEL AND THE STOCK MARKET

Market	Euronext Paris *since February 2015*
Mnemonic	POXEL
ISIN code	FR0012432516
Market Cap	143 M€*
Number of shares	28 703 692
Stock market price	5,00 €**
Minimum and maximum rates over 12 months	4,86 € – 7,85 €

** As of December 8, 2021*

SHAREHOLDER OWNERSHIP[1]



Key financials

As of 09/30/21 cash & cash equivalents:
EUR 37.2 million (USD 43.2 million)

ANALYST COVERAGE

Bryan Garnier	Jean-Jacques Le Fur
Degroof Petercam	David Seynnaeve
Jefferies	Lucy Codrington
JMP Securities	Jason Butler
Oddo BHF	Martial Descoutures

[1] As of November 2, 2021

[2] And affiliates

CONTACTS

Elizabeth Woo | Senior Vice President, Investor Relations & Communication
elizabeth.woo@poxelpharma.com
Aurélie Bozza | Investor Relations & Communication Director
aurelie.bozza@poxelpharma.com

NewCap | Investor and Media Relations
poxel@newcap.eu

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