September 21, 2017

Poxel Reports Results for the First Half 2017 and Provides Corporate Update

Poxel will host an investor conference call today to discuss the First Half 2017 results at 1 pm ET (7 pm CET). To participate in the call, please use the dial-in numbers: US: +1 877-887-4163 FR: +33 (0)172001510 UK: +44 2030432440

Access Code: 11730055#

LYON, France--(BUSINESS WIRE)-- POXEL SA (Euronext – POXEL - FR0012432516), a biopharmaceutical company focused on the development of innovative treatments for metabolic disorders, including type 2 diabetes, announced today its results for the first half of 2017 ended June 30, 2017, and provided a corporate update. As of June 30, 2017, cash and cash equivalents were EUR €34.9 million (USD $39.8 million).

“I am pleased to report that we have continued to make significant clinical and regulatory progress, expanded the depth of our management team and added a new member to our Board of Directors from Japan during the first half of 2017,” said Thomas Kuhn, CEO of Poxel. “For our lead program, Imeglimin, we announced robust efficacy results for the 299-patient Phase 2b study for the treatment of type 2 diabetes in Japan. We also strengthened Imeglimin’s profile and presented new mechanistic data showing its benefit in beta cell protection and detailed its unique insulin secretion pathway in response to glucose. Promising data was also presented at this year’s American Diabetes Association meeting demonstrating Imeglimin’s potential for cardiovascular protective properties to treat diabetic cardiomyopathy, a significant cardiovascular complication with limited treatment options.”

“Japan is a key focus and an integral part of our business strategy. We believe that Imeglimin’s unique profile could be very attractive given the specific needs of this important marketplace and the pathophysiology of Japanese patients,” said Thomas Kuhn, CEO of Poxel. “Due to Imeglimin’s safety and efficacy profile, it has the potential to be used as first-line therapy for type 2 diabetes in Japan for treatment naïve patients or in combination with other glucose lowering therapies, as well as for the elderly and sensitive populations. We are looking forward to initiating the Phase 3 program for Imeglimin in Japan during the fourth quarter of this year.”

“For our second program, PXL770, we recently initiated a Phase 1b multiple ascending dose study. We believe that PXL770 could have the potential to treat several chronic metabolic diseases, including those that affect the liver as well as diabetes and diabetes-related complications. We are currently evaluating potential indications for our clinical proof-of-concept program, which we plan to initiate in 2018,” continued Thomas Kuhn. “In addition, we are actively working to further leverage our internal capabilities and are currently

assessing additional development opportunities in the metabolic area."

Poxel First Half 2017 Highlights

Imeglimin

In preclinical and clinical studies, Imeglimin has demonstrated the potential to address the mitochondrial dysfunction at the core of type 2 diabetes pathophysiology. Imeglimin is the first orally available drug candidate that simultaneously targets all three key organs affected by diabetes: the pancreas, the liver and the muscles. Imeglimin has completed Phase 1 and Phase 2 development in over 1,200 subjects in the U.S., EU and Japan. Over the course of the first half of 2017, Imeglimin successfully completed several important milestones including:

Robust Efficacy Results from the Phase 2b study in Japan

- The Phase 2b randomized, double-blind, placebo-controlled study tested three doses of Imeglimin (500 mg, 1000 mg and 1500 mg) administered twice-daily for 24 weeks in 299 Japanese patients for the treatment of type 2 diabetes. The study achieved statistically significant results for its primary and secondary endpoints.
- The primary endpoint achieved statistical significance ($p<0.0001$) for the change from baseline in glycated hemoglobin (HbA1c) versus placebo in all treatment groups at 24 weeks. Placebo-adjusted HbA1c reduction was 0.52%, 0.94% and 1.00% for the 500 mg, 1000 mg and 1500 mg dose twice-daily, respectively. Overall, the study showed that Imeglimin was safe and well tolerated and the adverse event profile was consistent to what was observed in the U.S. and EU Phase 1 and 2 programs.

Additional Benefits Beyond Glucose Control

- Data presented at the 77th American Diabetes Association (ADA) Scientific Session demonstrated protective effects for diabetic cardiomyopathy, which is a significant cardiovascular complication that affects approximately 40 percent of type 2 diabetes patients and is associated with an increase in morbidity and mortality.[1] The data demonstrated that Imeglimin may have the potential to reduce the burden of this prominent cardiovascular complication in type 2 diabetes patients.
- In March 2017, Imeglimin successfully completed a thorough QT/QTc (TQT) cardiac safety study in 55 healthy subjects and no evidence of QT prolongation was observed. This study assesses a drug's risk of QT prolongation and its proarrhythmic potential.
- Data presented at the 9th Scientific Meeting of the Asian Association for the Study of Diabetes included mechanistic data showing Imeglimin's benefit on beta cell protection and its unique insulin secretion pathway in response to glucose. A comprehensive summary of the Phase 1 data in Japanese subjects was also presented demonstrating that Imeglimin was safe, well tolerated and exhibited a similar pharmacokinetic profile to what was observed in Caucasian subjects.

Regulatory Update

- Recently, Poxel met with the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan for the Imeglimin End of Phase 2 meeting to discuss its Phase 3 program plans and the data package required for a Japanese New Drug Application (JNDA)

submission. Based on constructive interactions and feedback from the PMDA, Poxel plans to move forward with its Phase 3 program during the fourth quarter of 2017.

- The Phase 3 program in Japan will consist of three pivotal studies, which include 1) a monotherapy study of double blind treatment versus placebo which is similar to the recently completed Phase 2b study, 2) a long-term safety study as a monotherapy and add-on to other oral therapies or GLP1 agonists, and 3) a long-term safety study as an add-on to insulin. These trials will be performed using the optimal dose of 1000 mg twice daily. To further differentiate Imeglimin's product profile, Poxel will also confirm Imeglimin's potential in sensitive patient populations, such as those with kidney-related complications due to type 2 diabetes.

PXL770

PXL770 is a first-in-class direct adenosine monophosphate-activated protein kinase (AMPK) activator. AMPK plays a key role as a master regulator of cellular energy, which turns on pathways that replenish energy and turns off pathways that consume energy, leading to the control of lipid metabolism, glucose homeostasis and inflammation. Based on this central metabolic role, targeting AMPK offers the opportunity to pursue a wide range of indications to treat chronic metabolic diseases,[2] including diseases that affect the liver, such as non-alcoholic steatohepatisis (NASH), as well as type 2 diabetes and diabetes-related complications, such as diabetic nephropathy.

- A Phase 1b multiple ascending dose (MAD) trial for PXL770 is currently underway. The MAD trial will include up to 76 subjects and evaluate the safety, tolerability and pharmacokinetics of PXL770 in at least four dose groups. Completion of the MAD trial is anticipated in early 2018.
- Results from the first part of the single ascending dose study indicate that PXL770 exhibited a favorable safety and tolerability profile with no reported serious adverse events.

Corporate

- Poxel expanded the depth of its management team during the first half of 2017 with the appointments of Anne Renevot as Chief Financial Officer and Christophe Arbet-Engels as Chief Medical Officer and Executive Vice President, Late Development & Medical Affairs. In addition, Kumi Sato was appointed to its Board of Directors. Ms. Sato will help support Poxel's corporate strategy for Imeglimin in Japan.
- In June 2017, ENYO Pharma SA reported that the Phase 1a single and multiple ascending dose trial evaluating EYP001 in healthy subjects has been completed. The results show that EYP001 was safe and well-tolerated at all doses studied in 80 subjects. The first Phase 1 study was designed to determine the safety, tolerability and pharmacokinetics of EYP001 in healthy subjects. Another ongoing Phase 1 study will evaluate the safety, food effect and PK of EYP001 in subjects with chronic HBV infection. EYP001 is an FXR agonist licensed to ENYO Pharma by Poxel.

Financial Statements for First Half 2017 (IFRS standards)

Poxel devotes the bulk of its resources to research and development activities. R&D expenses for the first half of 2017 totalled €6.3 million, mainly reflecting the clinical study

costs incurred for the Company's lead program, Imeglimin and its second compound, PXL770. The €2.2 million decrease in R&D expenses as compared to the first half of 2016 was mainly driven by completion of the Phase 2b clinical study for Imeglimin in Japan whose top line results were published in May 2017. The R&D costs are net of the R&D Tax Credit (CIR) that resulted in income of €1.6 million for the first half of 2017. The €0.5 million decrease in general and administrative (G&A) costs was mainly driven by non-recurrent 2016 costs related to financing activities. The financial expenses for the first half of 2017 totalled € 0.2 million, mainly reflecting foreign currency exchange loss. The net result for the financial period ending June 30, 2017 was a net loss of €9.7 million, as expected, compared to a net loss of €12.4 million in the corresponding period in 2016. On June 30, 2017, cash and cash equivalents were €34.9 million compared to €45.6 million on December 31, 2016.

Condensed Income Statement *In thousand €*

	30 June 2017	**30 June 2016**
Turnover	**-**	**-**
Net research and development expenses*	(6 259)	(8 470)
General and administrative expenses	(3 249)	(3 720)
Operating loss	**(**9 508**)**	**(**12 190**)**
Financial expenses/Financial income	(180)	(196)
Net loss	**(9 688)**	**(12 386)**

*Excludes R&D tax credit

Number of shares and voting rights as of June 30, 2017:

Month	Date	Total number of shares outstanding	Total of theoretical voting rights (1)	Total of exercisable voting rights (2)
June	6/30/2017	23,034,228	23,034,228	23,005,807

(1) The total number of theoretical voting rights (or "gross" voting rights) is used as the basis for calculating the crossing of shareholding thresholds. In accordance with Article 223-11 of the AMF General Regulation, this number is calculated on the basis of all shares to which voting rights are attached, including treasury shares whose voting rights have been suspended.
(2) The total number of exercisable voting rights (or "net" voting rights) is calculated without taking into account the treasury shares with suspended voting rights, in this case, shares held by the Company in the context of a liquidity contract agreement with ODDO.

Next financial press release: Q3-turnover and cash position October 16, 2017.

About Imeglimin
Imeglimin is the first clinical candidate in a new chemical class of oral agents called the

Glimins. Imeglimin has a unique mechanism of action (MOA) that targets mitochondrial bioenergetics. Imeglimin acts on the three main target organs involved in glucose homeostasis: the liver, muscle, and the pancreas. This MOA has the potential for glucose lowering benefits, as well as the potential to prevent endothelial and diastolic dysfunction, which can provide protective effects on micro- and macro-vascular defects induced by diabetes. The additional protective effect on beta-cell survival and function may lead to a delay in disease progression. This unique mode of action compared to existing treatments for type 2 diabetes makes Imeglimin a prime candidate in all stages of the current anti-diabetic treatment paradigm, including monotherapy or as an add-on to other glucose lowering therapies for the treatment of patients with type 2 diabetes.

About PXL770
PXL770 is a first-in-class direct adenosine monophosphate-activated protein kinase (AMPK) activator. AMPK plays a key role as a master regulator of cellular energy, which turns on pathways that replenish energy and turns off pathways that consume energy, leading to the control of lipid metabolism, glucose homeostasis and inflammation. Based on this 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 non-alcoholic steatohepatisis (NASH), as well as type 2 diabetes and diabetes-related complications, such as diabetic nephropathy.

About Poxel SA
Poxel uses its development expertise in metabolism to advance a pipeline of drug candidates focused on the treatment of metabolic disorders, including type 2 diabetes. We have successfully completed our Phase 2 clinical program for our first-in-class lead product, Imeglimin, which targets mitochondrial dysfunction, in the U.S., EU and Japan. Our second program, PXL770, a direct AMPK activator, is in Phase 1 development. We intend to generate further growth through strategic partnerships and pipeline development. (Euronext: POXEL, www.poxelpharma.com)

[1] Fitchett et al. European Journal of Heart Failure (2017)
[2] Source: Srivastava, R. A et al., (2012) Journal of Lipids Research 53, 2490- 2514

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