September 19, 2018

Poxel Reports Financial Results for the First Half 2018 and Provides Corporate Update

- **Executed strategic agreement for Imeglimin with Roivant Sciences, which included USD 35 million upfront payment, and potential for up to USD 600 million in regulatory and development milestone payments and sales-based payments plus royalties on net sales**
- **Roivant concurrently invested USD 15 million in Poxel through subscription to newly-issued ordinary shares at EUR 8.5 per share**
- **Phase 3 TIMES program for Imeglimin in Japan with partner Sumitomo Dainippon Pharma on track with initial data results anticipated beginning second quarter 2019**
- **Expanded metabolic pipeline through acquisition of PXL065 (DRX-065), a novel, clinical stage drug candidate for NASH, and other programs from DeuteRx LLC**

Poxel will host an investor conference call today to discuss the First Half 2018 results at 1:30 pm ET (7:30 pm CET). To participate in the call, please use the dial-in numbers: US: +1 6467224916 France: +33 (0) 172727403 UK: +442071943759 Access Code: 69674036#. For a replay of the call, please use: US +1 646-722-4969 France +33 (0)170710160 UK +44 2033645147 Access Code: 418789031#

Lyon, France, September 19, 2018 – POXEL S.A. (Euronext – POXEL - FR0012432516), a biopharmaceutical company focused on the development of innovative treatments for metabolic disorders, including type 2 diabetes and non-alcoholic steatohepatitis (NASH), announced today its results for the first half of 2018 ended June 30, 2018, and provided a corporate update. As of June 30, 2018, cash and cash equivalents were EUR 94.4 million (USD 110.1 million).

“This year has been a transformative year for Poxel. We have delivered on several significant corporate and clinical milestones, including a partnership for Imeglimin with Roivant Sciences in the US, Europe, and additional countries worldwide; the completion of enrollment for the Phase 3 TIMES 1 and TIMES 3 trials for Imeglimin for the treatment of type 2 diabetes in Japan; and the completion of the Phase 1 program for PXL770, which will be advancing into a Phase 2 program for the treatment of NASH,” said Thomas Kuhn, CEO of Poxel.

“Furthermore, with the recent acquisition of PXL065 (DRX-065) for NASH from DeuteRx, we will be one of only a few biotech companies with two NASH programs in clinical development. PXL065, an MPC inhibitor and PXL770, a direct AMPK activator, are drug

candidates that have the potential to treat the underlying root causes of liver disease. We believe these mechanisms as monotherapies or in combination-use together or with other agents have the potential to provide broad treatment of this disease. We expect to initiate the PXL770 Phase 2 program in first quarter of 2019 and pending successful completion of Phase 1 for PXL065, we plan to initiate a Phase 2 program in the second half of 2019. In addition, we are also exploring other opportunities from the DeuteRx metabolic portfolio," continued Thomas Kuhn.

Poxel First Half 2018 Update and Recent Highlights

Imeglimin

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. It has completed Phase 1 and Phase 2 development in over 1,200 subjects in the U.S., Europe and Japan and is in Phase 3 development in Japan. Over the course of the first half of 2018, Imeglimin successfully completed several important milestones.

Strategic Partnership Signed for Imeglimin in the U.S., Europe and Additional Countries Worldwide

- The strategic agreement with Roivant for the development and commercialization of Imeglimin in the U.S., Europe and additional countries worldwide will support Imeglimin's development and commercialization in the U.S., Europe and other countries outside of Poxel's partnership with Sumitomo Dainippon Pharma. The agreement included an upfront payment of USD 35 million (approximately EUR 28 million) as well as potential future development and regulatory milestone payments and sales-based payments of up to USD 600 million (approximately EUR 486 million*), and double-digit royalties on net sales.
- Roivant concurrently invested USD 15 million (approximately EUR 12 million) in Poxel through a subscription to newly-issued ordinary shares at EUR 8.5 per share.
- Activities with Roivant in 2018 to support the initiation of the Phase 3 program are under way and include differentiation studies to confirm Imeglimin's potential in sensitive patient populations, such as those with chronic kidney disease, as well as manufacturing of the drug product for use in the Phase 3 program.
- The goal is to initiate the Phase 3 program in the U.S. and Europe in 2019.

Progression of the Phase 3 TIMES Program

- Referred to as TIMES (**T**rials of **IM**eglimin for **E**fficacy and **S**afety), the Imeglimin Phase 3 program in Japan includes three pivotal trials to evaluate Imeglimin's efficacy and safety in approximately 1,100 patients.
- Patient enrollment for the TIMES 1 and TIMES 3 trials was completed. The TIMES 1 trial is a multicenter, double-blind, placebo-controlled, randomized, monotherapy study in over 200 Japanese patients with type 2 diabetes. The TIMES 2 trial is an open-label study to assess the long-term safety and efficacy of Imeglimin administrated as a monotherapy or combination therapy with existing hypoglycemic agents in approximately 700 Japanese patients with type 2 diabetes. The TIMES 3 trial is a double-blind, placebo-controlled, randomized study with an open-label extension period to evaluate the efficacy and safety of Imeglimin in combination with insulin in

over 200 Japanese patients with type 2 diabetes and inadequate glycemic control on insulin therapy. Patient enrollment for TIMES 2 is expected to be completed during the second half of 2018.
- Phase 3 data results for the TIMES 1 trial are anticipated during the second quarter of 2019 and the TIMES 2 and TIMES 3 results are expected in the second half of 2019.

Data at the American Diabetes Association 78th Scientific Sessions

- Data on Imeglimin's effect on pancreatic beta-cell protection was presented at the American Diabetes Association 78th Scientific Sessions. Imeglimin was observed to protect and preserve human beta-cells from cell death from fructose- and glucose-induced toxicity by inhibiting mitochondrial Permeability Transition Pore opening (mPTP). This data highlights Imeglimin's potential to delay type 2 diabetes disease onset and progression through the preservation of beta-cell mass.

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 and modifying its activity 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). PXL770 is advancing into a Phase 2a program for the treatment of NASH.

- The Phase 1b multiple ascending dose (MAD) trial for PXL770 was observed to have a favorable safety and pharmacokinetic profile. In this study, after 10-day repeated administration of PXL770 once- or twice-daily, from 60 mg to 500 mg, there were no serious adverse events or adverse events leading to withdrawal.
- Preclinical proof-of-concept data presented at the Global NASH Congress 2018 highlighted PXL770 as a novel therapeutic approach in non-alcoholic fatty liver diseases (NAFLD), improving core disease symptoms. PXL770 was observed to significantly reduce liver steatosis and NAS score following eight weeks of treatment vs control and significantly reduce expression of a panel of key genes associated with fibrosis.
- Based on the results in the Phase 1b, Poxel is preparing to initiate a Phase 2a proof-of-concept program. This program will include a randomized, double-blind, placebo-controlled, parallel-group study that will assess the efficacy and safety of PXL770 versus placebo in approximately 100 patients with NAFLD.

PXL065 (DRX-065)

PXL065 (deuterium-stabilized R-pioglitazone) is a mitochondrial pyruvate carrier (MPC) inhibitor. PXL065 is the R-stereoisomer (single isomer) of pioglitazone. Pioglitazone, a drug approved for the treatment of type 2 diabetes, has demonstrated efficacy in NASH and is currently the only drug recommended in practice guidelines for biopsy-proven NASH patients[1]. However, pioglitazone's use has been limited in NASH due to its PPARg-related side effect profile, which includes weight gain, bone fractures and fluid retention. PXL065, a novel patent-protected drug candidate, offers a new approach for the treatment of NASH.

- Poxel acquired on August 30, 2018, exclusive, worldwide ownership from DeuteRx to PXL065 (deuterium-stabilized R-pioglitazone), a clinical stage program being pursued

for the treatment of NASH, as well as additional programs, including deuterated drug candidates for metabolic, specialty and rare diseases. Poxel plans to advance PXL065 into proof-of-concept studies for the treatment of NASH in 2019.
- Poxel paid DeuteRx an upfront payment composed of EUR 6.8 million (USD 8 million) in cash plus 1.29 million in new ordinary shares of Poxel common stock, representing 4.99 percent of Poxel's issued capital. DeuteRx is also eligible to receive development, regulatory and sales-based milestone payments, and royalties on net sales.
- Based upon preclinical and Phase 1 results to date, PXL065 is anticipated to show a better therapeutic profile than pioglitazone, including the potential for enhanced efficacy and a reduction of side effects, such as those associated with peroxisome proliferator-activated receptor gamma (PPAR-γ) activation.

Financial Statements for First Half 2018 (IFRS Standards)

Revenue

Poxel reported revenues of EUR 37.5 million for the first half of 2018, as compared with no revenue during the same period in 2017.

€ millions	H1 2018	H1 2017	**Variance**
Roivant Agreement	8.1	-	8.1
Sumitomo Agreement	29.4	-	29.4
Total revenues	37.5	-	37.5

The revenue reflects a portion of the EUR 36 million upfront payment received from Sumitomo Dainippon Pharma relating to the strategic corporate partnership announced on October 30, 2017, and the USD 35 million (EUR 28 million) upfront payment associated with the corporate partnership announced with Roivant Sciences on February 12, 2018, net of Poxel's financial contribution to Roivant. In addition, the revenue also reflects the Imeglimin Phase 3 TIMES program costs in Japan incurred during the first half of 2018 that were re-invoiced to Sumitomo Dainippon Pharma. Both the upfront payment from Sumitomo Dainippon Pharma and re-invoiced costs of the Phase 3 TIMES program are recognized according to the percentage of completion of this program.

Income Statement

Poxel devotes the bulk of its resources to research and development (R&D) activities. R&D expenses totaled EUR 27.4 million for the first half of 2018, as compared to EUR 6.3 million for the corresponding period in 2017. The R&D expenses mainly reflect the EUR 22.5 million clinical study costs incurred in the Imeglimin Phase 3 TIMES program over the period. To a lesser extent, they also reflect the clinical study costs incurred for PXL770, Poxel's second clinical-stage program. This almost 4-fold increase, as compared to the first half of 2017, is primarily driven by the Phase 3 TIMES program that was initiated in late December 2017.

The R&D costs are net of the R&D Tax Credit (CIR) that resulted in income of EUR 1.5 million for the first half of 2018 as compared to EUR 1.6 million for the first half of 2017.

General and administrative expenses totaled EUR 3.6 million as of June 30, 2018, as compared to EUR 3.2 million for the first half of 2017.

The financial income amounted to a gain of EUR 0.8 million as of June 30, 2018, as compared to a loss of EUR 0.2 million for the first half of 2017, which primarily reflects foreign exchange fluctuations.

The net result for the financial period ending June 30, 2018 was a net income of EUR 7.3 million, as compared to a net loss of EUR 9.7 million in the corresponding period in 2017.

Condensed Income Statement *In thousand €*

	30 June 2017	**30 June 2018**
Turnover	**-**	**37 463**
Net research and development expenses**	(6 259)	(27 442)
General and administrative expenses	(3 249)	(3 614)
Operating gain (loss)	**(9 508)**	**6 406**
Financial income (expenses)	(180)	850
Net income (loss)	**(9 688)**	**7 256**

**Net of R&D tax credit

Cash

As of June 30, 2018, cash and cash equivalents were EUR 94.4 million (USD 110.1 million) as compared to EUR 53.4 million ($64.1 million) as of December 31, 2017.

This figure includes the $50 million upfront payment and investment received from Roivant Sciences (approximately EUR 40 million) in February 2018.

Next financial press release: Q3-turnover and cash position October 16, 2018.

About Imeglimin

Imeglimin is the first clinical candidate in a new chemical class of oral agents called Glimins by the World Health Organization. Imeglimin has a unique mechanism of action ("MOA") that targets mitochondrial bioenergetics. Imeglimin acts on all three key organs which play an important role in the treatment of type 2 diabetes: the liver, muscles and the pancreas, and it has demonstrated glucose lowering benefits by increasing insulin secretion in response to glucose, improving insulin sensitivity and suppressing gluconeogenesis. This MOA has the potential to prevent endothelial and diastolic dysfunction, which can provide protective effects on micro- and macro-vascular defects induced by diabetes. It also has the potential for protective effect on beta-cell survival and function. This unique MOA offers the potential opportunity for Imeglimin to be a candidate for the treatment of type 2 diabetes in almost all stages of the current anti-diabetic treatment paradigm, including monotherapy or as an add-on to other glucose lowering therapies.

About PXL770

PXL770 is a first-in-class direct adenosine monophosphate-activated protein kinase (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 non-alcoholic steatohepatitis (NASH).

About PXL065

PXL065 is deuterium-stabilized R-pioglitazone. Pioglitazone is the most extensively studied drug for NASH and has demonstrated "resolution of NASH without worsening of fibrosis" in a Phase 4 trial.[2] 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).[1] Pioglitazone's 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 (stereoisomers) that interconvert *in vivo*. Using deuterium, DeuteRx stabilized each stereoisomer and characterized their dramatically different pharmacological properties. In *in vitro* studies, PXL065 has been shown to target MPC as an inhibitor. In preclinical models, PXL065 exhibits the anti-inflammatory activity and NASH efficacy 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, PXL065 is expected to exhibit a better therapeutic profile than pioglitazone for NASH.

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 and non-alcoholic steatohepatitis (NASH). We have successfully completed the Phase 2 clinical program for our first-in-class lead product, Imeglimin, which targets mitochondrial dysfunction, in the U.S., Europe and Japan. Together, with our partner Sumitomo Dainippon Pharma, we are conducting the Phase 3 Trials of IMeglimin for Efficacy and Safety (TIMES) program for the treatment of type 2 diabetes in Japan. Our partner Roivant Sciences is responsible for Imeglimin's development and commercialization in countries outside of Poxel's partnership with Sumitomo Dainippon Pharma, including the U.S. and Europe. PXL770, a first in class direct adenosine monophosphate-activated protein kinase (AMPK) activator, is advancing into a Phase 2a proof-of-concept program for the treatment of NASH. PXL770 could also have the potential to treat additional metabolic diseases. PXL065 (deuterium-stabilized R-pioglitazone), a mitochondrial pyruvate carrier (MPC), is in Phase 1 and being developed for the treatment of NASH. Poxel also has additional earlier-stage programs, including deuterated drug candidates for metabolic, specialty and rare diseases. We intend to generate further growth through strategic partnerships and pipeline development. (Euronext: POXEL, www.poxelpharma.com)

*Converted at the exchange rate at the date of the agreement.

1. J Hepatol. 2016, 64(6),1388-402; Hepatology 2018, 67, 328-357
2. Cusi, et al., Ann Intern Med. 2016, 165(5), 305-315

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