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# Poxel Reports Results for First Half 2016 and Provides Corporate Update

New Imeglimin Data Continues to Differentiate its Unique Product Profile

Successful Capital Raise Provides Funds to Advance Imeglimin to Phase 3 Development in Japan

LYON, France--(BUSINESS WIRE)-- POXEL SA (Euronext – POXEL - FR0012432516), a biopharmaceutical company focused on the development of innovative treatments for type 2 diabetes, today announced its results for the first half of 2016 ended June 30, 2016, and provided a corporate update.

“We have made significant progress in continuing to build out Imeglimin’s product profile and scientifically differentiate its mechanism of action from other drugs, as evidenced by the new data presented and published this year,” said Thomas Kuhn, CEO of Poxel. “Additionally, we have continued to advance Imeglimin’s Phase 2b trial in Japan and have recruited approximately 300 patients who have been randomized into the trial. Japan is a key focus for Poxel and is an integral part of our business strategy. Japan represents the second largest single market for type 2 diabetes with approximately \$4 billion in annual sales and growth of almost 20 percent annually. Asia, in broader terms, is considered the most important geographic location with regards to treating the diabetes pandemic in the future.”

## Highlights for the First Half of 2016:

### Imeglimin

- The Company achieved several important milestones in developing Imeglimin for the Asian market and has key upcoming events.
  - The Imeglimin dose-ranging, randomized, double-blind, placebo-controlled Phase 2b study with approximately 300 naïve and pre-treated Japanese patients is fully enrolled and patients have been randomized into 24 weeks of treatment. The primary endpoint of the trial is efficacy measured by change in glycated haemoglobin A1c concentrations.
  - The Japan Phase 2b Imeglimin results are anticipated during the second quarter of 2017.
  - Poxel expects to be in the position to initiate the Phase 3 development program in Japan during the fourth quarter of 2017.
- Poxel has ongoing discussions with the European Medicines Agency (EMA) for the Phase 3 program in Europe as it finalizes its plan for this region. In addition, the Company remains engaged with the U.S. Food and Drug Administration and Japanese

Pharmaceuticals and Medical Devices Agency as it prepares for the Phase 3 program in these countries.

- At the American Diabetes Association meeting in June 2016, Poxel presented compelling preclinical data showing Imeglimin's dual mechanism of action. Over the past year, the Company has made significant progress in understanding how Imeglimin improves both insulin sensitivity and secretion, which are the two key defects that cause type 2 diabetes. The new discovery that Imeglimin increases the nicotinamide adenine dinucleotide (NAD) synthesis, a pivotal molecule for mitochondrial function, further elucidates Imeglimin's unique mechanism of action on insulin secretion in response to glucose.
- In July, findings published in the *American Journal of Physiology, Endocrinology and Metabolism* demonstrate that Imeglimin primarily lowers glucose levels by increasing glucose-stimulated insulin secretion in a preclinical model. These findings highlight that Imeglimin's effect on insulin secretion in response to glucose is a direct effect as shown in isolated islets that act through amplification of mitochondrial metabolism-dependent signals. This data helps to explain the absence of hypoglycemia seen in clinical trials to date.
- At the upcoming European Association of Study for Diabetes (EASD) on September 14<sup>th</sup> in Munich, Poxel will present new preclinical results showing how Imeglimin improves vascular dysfunction in a type 2 diabetes animal model. Endothelium dysfunction is the first step in the development of cardiovascular diseases.

## PXL770

- PXL770 is a first-in-class direct adenosine monophosphate-activated protein kinase (AMPK) activator, a key enzyme in energy metabolism acting as an energy sensor regulating glucose and lipid levels. AMPK activation is considered to mimic the effects of long-term exercise and plays an important role in diabetes management, especially for patients with cardiovascular risk factors.
- At the upcoming 2016 EASD meeting, Poxel will present new PXL770 data showing effect on *de novo* lipid synthesis and on weight and fat mass loss in an animal model of diabetes and obesity.
- PXL770 is in Phase 1 study in healthy volunteers. The single ascending dose trial enrolled 64 healthy male subjects to assess safety, tolerability and pharmacokinetics of six single ascending oral doses of PXL770. Poxel announced in June 2016 that results from the first part of the study indicate that PXL770 exhibits a favorable safety and tolerability profile with no serious adverse events reported or safety signal.
- During the Phase 1 study, Poxel observed a different metabolic pattern in humans compared to animals that were treated with PXL770. Therefore, based on regulatory guidelines, Poxel will need to further evaluate the profile of the metabolites, which may be pharmacologically active, prior to the start of the second part of the Phase 1 study. As a result of this additional preclinical work, the second part of the Phase 1b study will be delayed until 2017.

## Corporate

- In July 2016, Poxel closed a capital increase of 3,400,000 new ordinary shares for a total amount of €26.5 million. The Company expects that the net proceeds are sufficient to provide the Company with operating cash to early 2019, exclusive of any

costs associated with funding a Phase 3 program for Imeglimin outside of Japan. The capital increase was subscribed for by prominent institutional investors in the United States and Europe.

- During the first quarter of 2016, the Company strengthened its Board of Directors with the addition of Pierre Legault, who is a member of the Board of Directors of several U.S.-listed biotechnology companies, and Janice Bourque, Managing Director of Hercules Technology Growth Capital. Pierre was appointed as the new Chairman of Poxel's Board of Directors in April, former chair Thierry Hercend will continue to support Poxel as a member of the Board.
- In addition, Jonae Barnes, who is based in Boston, joined the Company as Senior Vice President, Investor Relations and Public Relations. Jonae is working closely with Noah Beerman, Poxel's Executive Vice President, Business Development and President of U.S. Operations. Poxel intends to continue to expand in the United States from its Boston location, which is a global leading center in drug development and innovation. The Company also plans to expand its presence in Japan with additional hires to support the Phase 3 program in Japan together with Dr. Yohjiro Itoh, who is leading Poxel's clinical and regulatory operations in Asia.

### **Financial Statements for the First Half of 2016 (IFRS standards)**

Group revenues for H1 2016 are nil. Following the 2015 initial public offering (IPO), Poxel has devoted the bulk of its operating costs to research and development (R&D) and has increased its R&D efforts and therefore expenses in H1 2016, as compared to H1 2015. The variance from H1 2015 to H1 2016 reflects mainly the Phase 2b study costs in Japan for the Company's lead product, Imeglimin, and the initial Phase 1 costs for its second compound, PXL770. Both studies were initiated at the end of 2015. Poxel also incurred significant costs for chemistry, manufacturing and controls (CMC) activities to prepare the active pharmaceutical ingredient (API) supply for the upcoming Phase 3 study in Japan. Poxel was awarded subsidies (an R&D Tax Credit (CIR)) that represented income of €1.7 million in H1 2016, as compared to €0.9 million in H1 2015. The R&D tax credit did not increase at the same rate as R&D expenses increased due to the fact that the Phase 2b study in Japan is not eligible for tax credits, since it is being conducted outside of Europe. The increase in general and administrative (G&A) costs mainly resulted from various non-recurrent costs. Personnel costs also increased as a result of preparation for future work in Japan and in the United States. In both periods, financial charges were mainly driven by the interest expense linked to the venture loan and the interest income linked to Poxel's treasury. The net result for the financial period ending June 30, 2016 showed a loss of €12.4 million, as compared to a loss of €5.2 million in the corresponding period in 2015. On June 30, 2016, the cash and cash equivalents amounted to €32.1 million (compared to €42.4 million on December 31, 2015 and €29.5 million on June 30, 2015). The cash utilization rate was €1.7 million per month. All of the Company's financial results for H1 2016 were all in line with management's expectations.

### **Income Statement (consolidated)**

<i>In thousand €</i>	<b>June 30, 2016</b>	<b>June 30, 2015</b>
<b>Turnover</b>	-	<b>50</b>
Research and development expenses	(10 140)	(3 358)
Subsidies	1 669	948
General and administrative expenses	(3 719)	(2 676)
<b>Operating loss</b>	<b>(12 190)</b>	<b>(5 036)</b>
Financial expenses	(363)	(391)
Financial income	167	196
<b>Net loss</b>	<b>(12 386)</b>	<b>(5 231)</b>

#### **Number of shares and voting rights as at the end of June 2016:**

Date	Total number of shares outstanding	Total of theoretical voting rights (1)	Total of theoretical voting rights (2)
June 30, 2016	19,550,228	19,550,228	19,527,878

(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 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 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 Financial Sales and Corporate Update, October 21, 2016

#### **About Poxel SA**

Poxel uses its development expertise in metabolism to advance a pipeline of drug candidates focused on the treatment of type 2 diabetes. We have successfully completed our

Phase 2 trials for our first-in-class lead product, Imeglimin, which targets mitochondrial dysfunction, in the U.S. and EU and have fully enrolled a Phase 2b clinical study in 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)

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