

April 23, 2018



## Poxel Announces First Quarter 2018 Financial Update

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 and non-alcoholic steatohepatitis (NASH), today announced its cash position and revenue for the first quarter of 2018.

As of March 31, 2018, cash and cash equivalents were EUR 91.6 million (USD 112.8 million).

For the first quarter ending March 31, 2018, Poxel reported revenues of EUR 18.3 million. 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 program costs in Japan incurred during the first quarter that were re-invoiced to Sumitomo Dainippon Pharma. Both the upfront payment from Sumitomo Dainippon Pharma and re-invoiced costs of the Phase 3 **T**rials of **I**meglimin for **E**fficacy and **S**afety (TIMES) program are recognized according to the percentage of completion of this program.

"I am very pleased to report that we achieved several significant corporate and clinical milestones during the first quarter. In February, we signed a corporate partnership for Imeglimin with Roivant Sciences for the U.S., Europe and other countries worldwide. When combined with the Sumitomo Dainippon Pharma partnership, this represents a total upfront payment of EUR 76 million (USD 92\* million), which includes the equity investment of USD 15 million from Roivant, and potential future milestone and sales-based payments of up to approximately EUR 705 million (USD 857\* million) plus royalties on net sales," said Thomas Kuhn, CEO of Poxel. "In addition, we made substantial progress for Imeglimin in Japan advancing the three pivotal Phase 3 TIMES trials and we are on track for the data readout in 2019 and the Japanese New Drug Application submission in 2020. For the U.S. and Europe, we are working closely with Roivant Sciences on Phase 3-related activities with the goal to initiate the Phase 3 program in 2019."

"For our second program, PXL770, we are completing the Phase 1 multiple ascending dose study and the data is on track for mid-year. We believe that PXL770 has the potential to treat several chronic metabolic diseases, including those affecting the liver, such as NASH," added Thomas Kuhn. "During the second half of 2018, we are planning to initiate a Phase 2a proof-of-concept study in patients with nonalcoholic fatty liver disease (NAFLD), a condition where fat builds up in the liver and of which NASH is a severe form. PXL770 may be

differentiated from other compounds in development for liver diseases since targeting AMPK activation has the potential to also treat NASH comorbidities, specifically targeting cardiovascular risk factors, such as hyperglycemia, insulin resistance, dyslipidemia, inflammation and obesity. Additionally, we are actively working to further leverage our internal capabilities and are assessing additional development opportunities in the metabolic area.”

### **Planned Presentations at the Following Upcoming Events**

- William Blair Phase 3 Conference, May 3, New York City, NY
- UBS Global Healthcare Conference, May 21-23, New York City, NY
- Gilbert Dupont Healthcare Forum, May 29, Paris, France
- Jefferies Global Healthcare Conference, June 5-8, New York City, NY
- American Diabetes Association Meeting, June 22-26, Orlando, FL
- Kepler Cheuvreux Biotech Days, June 20, Paris, France
- JMP Securities Life Sciences Conference, June 20-21, New York City, NY

**Next financial press release:** July 10, 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 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 **IM**eglimin for **E**fficacy and **S**afety (TIMES) program for the treatment of type 2 diabetes in Japan. Our partner Roivant Sciences will be responsible for Imeglimin's development and commercialization in countries outside of Poxel's partnership with Sumitomo Dainippon Pharma, including the U.S. and Europe. Our second program, PXL770, a first in class direct adenosine monophosphate-activated protein kinase (AMPK) activator, is in Phase 1 and we plan on developing it for the treatment of NASH. PXL770 could also have the potential to treat additional metabolic diseases. We intend to generate further growth through strategic partnerships and pipeline development. (Euronext: POXEL, [www.poxelpharma.com](http://www.poxelpharma.com))

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

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