

July 10, 2018



Poxel Announces Second Quarter and First Half 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 second quarter and six months ended June 30, 2018.

As of June 30, 2018, cash and cash equivalents were EUR 94.4 million (USD 110.1 million).

Poxel reported revenues of EUR 19.2 million for the quarter ended June 30, 2018 and EUR 37.5 million for the six months ended June 30, 2018 compared with no revenues during the same periods in 2017.

<i>EUR millions</i>	Q1 2018	Q2 2018	H1 2018	Q1 2017	Q2 2017	H1 2017
Roivant Agreement	8.1	-	8.1	-	-	-
Sumitomo Agreement	10.2	19.2	29.4	-	-	-
Total revenues	18.3	19.2	37.5	-	-	-

Unaudited data

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 semester that were re-invoiced to Sumitomo Dainippon Pharma. Both the upfront payment from Sumitomo Dainippon Pharma and re-invoiced costs of the Phase 3 Trials of **Imeglimin** for **Efficacy** and **Safety** (TIMES) program are recognized according to the percentage of completion for this program.

"I am very pleased to report that during the quarter we made substantial progress for Imeglimin in Japan and continued to advance the three pivotal Phase 3 TIMES trials. The TIMES 1 trial is fully enrolled, and TIMES 2 and TIMES 3 are expected to be fully enrolled

during the second half of 2018. We are on track for the data readout in 2019, beginning with the TIMES 1 efficacy study readout during the second quarter of 2019. We are continuing to work closely with our partner Sumitomo Dainippon Pharma in preparing for the Japanese New Drug Application submission in 2020,” said Thomas Kuhn, CEO of Poxel. “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 to be released in July. We believe that PXL770 has the potential to treat liver diseases, such as NASH, and could have the potential to treat additional metabolic diseases,” added Thomas Kuhn. “We are preparing for the initiation of a Phase 2a proof-of-concept program 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 provide benefits to the three key pathophysiology processes involved in NASH development, which include liver steatosis, inflammation and fibrosis. Additionally, it also could treat NASH comorbidities, specifically targeting cardiovascular risk factors, such as hyperglycemia, insulin resistance, dyslipidemia, inflammation, and obesity. In parallel, we are actively working on further leveraging our internal capabilities and are assessing additional development opportunities in the metabolic area to broaden our pipeline.”

Planned Presentations at the Following Upcoming Events

Goodwin, Solebury Trout, and NASDAQ European Biotech Investor Day, July 19, 2018, New York City, New York

Trout CEO Roundtable, August 19, 2018, Hamptons, New York

European Society of Cardiology 2018, August 25-29, 2018, Munich, Germany

H.C. Wainwright 20th Global Investment Conference, September 4-6, 2018, New York City, New York

AMPK from Mechanisms to New Therapies, September 30-October 4, 2018, Ontario, Canada

Next financial press release: 2018 First Half Year Statement, September 19, 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 **T**rials **I**meglimin 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)

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

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Source: POXEL SA