October 21, 2016

Poxel Announces Third Quarter 2016 Financial Results and Corporate Update

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 cash position and financial results for the third quarter of 2016. As of September 30, 2016, cash and cash equivalents were EUR 51.1 million. This figure includes the net proceeds of a private placement completed in July 2016 that provided an additional EUR 24.1 million. With its current cash and cash equivalents, the Company has a cash runway to early 2019.

Poxel has continued to advance its 2016 business plan and move forward with its four key value drivers, which include: (1) the development of Imeglimin in Asia using Poxel's own resources; (2) the continued development of Imeglimin in Europe and the United States, for which it is seeking a development and commercial partner; (3) the development of PXL770; and (4) continuing to leverage Poxel's research capabilities and portfolio.

Imeglimin has completed Phase 2 development in over 850 subjects in the US and EU and is currently being studied in a 300-patient Phase 2b clinical trial in Japan. PXL770, a first-in-class direct AMPK activator, which regulates cellular energy metabolism and is considered to mimic the effects of long-term exercise, is in Phase 1 clinical development.

"We continue to make meaningful progress with the Imeglimin Phase 2b trial in Japan and are further demonstrating its differentiating benefits. At this year's European Association for the Study of Diabetes meeting, we presented promising new data showing the potential for beneficial protective effects on vascular dysfunction, which is key in the treatment of type 2 diabetes. Recently, we also presented interesting new data supporting Imeglimin's dual novel mechanistic approach of increasing glucose-dependent insulin secretion and improving insulin sensitivity (efficacy). In addition, we published mechanistic data relating to insulin secretion from a Yale-led study," said Thomas Kuhn, CEO of Poxel. "Through mid-2017, we are on track to deliver the Phase 2b results in Japan and plan to publish and present several preclinical and clinical results further demonstrating Imeglimin's glucose lowering benefits as well as cardiovascular and beta cell benefits that we believe will continue to differentiate it from other drugs in development and on the market to treat type 2 diabetes."

As expected, Poxel did not generate revenues in the third quarter of 2016, corresponding to the Company's forecasts.

3Q Highlights and Initiatives

Imeglimin

- Poxel achieved an important clinical milestone during the third quarter for Imeglimin in the Asian market and has significant upcoming events.
    - During the third quarter, the Imeglimin dose-ranging, randomized, double-blind, placebo-controlled Phase 2b study with approximately 300 naïve and pre-treated Japanese patients became 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 clinical results are expected to be announced 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.
- During the third quarter, Poxel continued its discussions with the European Medicines Agency (EMA) for the Phase 3 program in Europe, and the Company is close to finalizing 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.
- Poxel has also initiated several studies to strengthen Imeglimin's product profile, specifically related to its benefits beyond glucose lowering, targeting cardiovascular function and beta cell function preservation. In addition, a safety trial to assess the effect of Imeglimin on QT prolongation, which is a heart conduction disorder that can cause serious irregular heart rhythms (arrhythmias), has also been initiated. This safety study is a requirement for drug candidates with chronic use indications.
- In July, findings from a study led by Yale School of Medicine published in the *American Journal of Physiology, Endocrinology and Metabolism* demonstrated that Imeglimin primarily lowers glucose levels by increasing glucose-stimulated insulin secretion in a dedicated preclinical model. These findings highlight that Imeglimin's effect on insulin secretion in response to glucose is a direct effect that acts through amplification of mitochondrial metabolism-dependent signals. These data also help to explain the absence of hypoglycemia seen in clinical trials to date.
- At the European Association of Study for Diabetes (EASD) in September, Poxel presented preclinical data for Imeglimin that represent significant progress in further understanding its benefits beyond glycemic control. Specifically, the potential for beneficial protective effects in the early stages of vascular dysfunction, which is key in the treatment of type 2 diabetes.

PXL770

- At the 2016 EASD meeting, Poxel presented 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 a 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. 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, as 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 completed a private placement of 3,400,000 new ordinary shares, which raised net proceeds of EUR 24.1 million. The Company expects that the proceeds of the private placement will be 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 new shares were subscribed for by prominent US and European institutional investors.

Planned Attendance at the Following Events

- Bio-Europe, Cologne, November 7-9, 2016
- Jefferies Conference, London, November 16-17, 2016
- Oppenheimer 2016 Life Sciences Summit, New York City, November 29, 2016
- Oddo Mid-Cap Forum, Lyon, January 5-6, 2017
- JP Morgan Healthcare Conference, San Francisco, January 9-12, 2017

Next financial press release: Q4-2016 turnover and cash position, January 27, 2017

About Imeglimin

Imeglimin is the first in a new chemical class of oral anti-diabetic agents, the Glimins. Imeglimin acts on the three main target organs involved in glucose homeostasis: the liver, muscle, and the pancreas. Imeglimin has a unique mechanism of action that targets mitochondrial bioenergetics. This has the potential for glucose lowering benefits, as well as the potential to prevent endothelial dysfunction, which can provide protective effects on micro- and macro-vascular defects induced by diabetes, and benefits on beta cell protection and function, which can delay disease progression. This distinct mode of action compared to existing treatments for type 2 diabetes makes Imeglimin a prime candidate in monotherapy and to complement other treatments such as metformin or sitagliptin.

About PXL770

PXL770 directly activates adenosine monophosphate-activated protein kinase (AMPK), an enzyme that acts as an energy sensor and regulator, maintaining cellular homeostasis, thus playing an important role in the management of diabetes. In addition to its anti-diabetic properties, PXL770 has the potential to treat lipid-related abnormalities, which are present in a vast majority of diabetic patients and are the cause of cardiovascular incidents among this population, as well as other metabolic disorders.

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 clinical program 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, www.poxel.com)

View source version on businesswire.com:
http://www.businesswire.com/news/home/20161020006246/en/

Poxel SA
Jonae R. Barnes, +1 617-818-2985
Senior Vice President, Investor Relations and Public Relations
jonae.barnes@poxelpharma.com
or
Investor relations / Media - EU/US
MacDougall Biomedical Communications
Gretchen Schweitzer or Stephanie May, + 49 89 2424 3494 or + 49 175 571 1562
smay@macbiocom.com
or
Investor relations / Media - France
NewCap
Florent Alba/Nicolas Mérigeau, + 33 1 44 71 98 55
poxel@newcap.fr

Source: POXEL SA