

July 15, 2024



# Poxel Provides an Update on Its Financial Position for the Second Quarter and First Half of 2024 and Announces the Rescheduling of Its Annual General Meeting

- Patent Term Extension (PTE) approved in Japan for 2 patents related to TWYMEEG<sup>®</sup>, extending the product patent life until 2036
- Exclusive discussions being finalized with a leading investor to monetize royalties from sales of TWYMEEG<sup>®</sup> (Imeglimin) in Japan
- As of June 30, 2024, cash and cash equivalents amounted to EUR 2.8 million (USD 3 million<sup>1</sup>)
- Cash horizon estimated to be sufficient until the completion of the transaction, including only the tranches already drawn down or fully available under the equity-linked financing facility with IRIS
- Rescheduling of the Annual General Meeting 2024, subject to the publication of the full-year results for the year ended December 31, 2023

LYON, France--(BUSINESS WIRE)-- Regulatory News:

[POXEL SA](#) (Euronext : POXEL - FR0012432516), a clinical stage biopharmaceutical company developing innovative treatments for chronic serious diseases with metabolic pathophysiology, including non-alcoholic steatohepatitis (NASH) and rare metabolic disorders, today publishes its cash position, provides an update on its financial situation for the second quarter and first half of 2024, ending June 30, 2024, reviews its activities on June 30, 2024 and announces the rescheduling of its Annual General Meeting 2024, in view of the postponement of the closing of its social and consolidated financial statements for the year ended December 31, 2023.

**Thomas Kuhn, Chief Executive Officer of Poxel**, stated: "TWYMEEG<sup>®</sup>'s commercialization in Japan continues to gain momentum, supported by many scientific papers and articles in Japanese journals, some of which were or will be presented at international scientific congresses. In parallel with the expected finalization of our exclusive financing discussions based on the monetization of royalties from TWYMEEG<sup>®</sup> sales in Japan, the additional protection granted to TWYMEEG<sup>®</sup> until 2036 potentially represents a further opportunity for the product".

## **TWYMEEG<sup>®</sup> (Imeglimin)**

### **Clinical development, intellectual property and scientific publications**

- The Long-Term, 52-week, Open-label, Phase 4 Study conducted by Sumitomo Pharma of Imeglimin in Japanese Type 2 Diabetic Patients with Renal Impairment is currently ongoing in Japan to strengthen TWYMEEG<sup>®</sup> profile in this key subpopulation. Top line results are expected soon.
- On May 29, 2024, the Japanese Patent Office approved the remaining two PTE applications, granting Poxel an extension to patents n°5542066 and n°5758010, protecting Imeglimin's synthesis process.
- Several scientific presentations on TWYMEEG's<sup>®</sup> innovative mechanism of action and potential additional benefits, in addition to its anti-diabetic activity were shared at the 67<sup>th</sup> Annual Meeting of the Japanese Diabetes Society (JDS), held in Tokyo, Japan, from May 17 to 19, 2024, and at the 84<sup>th</sup> Scientific Sessions of the American Diabetes Association in Orlando, Florida. New preclinical and clinical data will be presented at the 60<sup>th</sup> Annual Congress of the European Association for the Study of Diabetes (EASD).

### **Cash and cash equivalents in the second quarter and first half of 2024**

As of June 30, 2024, total cash and cash equivalents amounted to EUR 2.8 million (USD 3 million<sup>1</sup>), compared with EUR 2.3 million (USD 2.6 million<sup>2</sup>) as of December 31, 2023 (unaudited data). Net financial debt (excluding IFRS16 impacts and derivative debts) amounted to EUR 46.6 million as of June 30, 2024, compared with EUR 45.6 million as of December 31, 2023 (unaudited data).

| <i>EUR (thousands)</i>           | <b>Q2 2024</b> | <b>Q4 2023</b> |
|----------------------------------|----------------|----------------|
| Cash                             | 2,812          | 2,341          |
| Cash equivalents                 | -              | -              |
| <b>Cash and cash equivalents</b> | <b>2,812</b>   | <b>2,341</b>   |

*Unaudited data.*

### **Finalization of exclusive discussions with a leading investor to monetize royalties from sales of TWYMEEG<sup>®</sup> (Imeglimin) in Japan and cash runway**

With the priority objective of relaunching its R&D activities and executing its strategic plan in rare diseases, the Company has focused in recent months on securing additional financing, in particular non-dilutive solutions. In this context, the Company is currently finalizing exclusive negotiations with a leading investor to monetize royalties from TWYMEEG<sup>®</sup> (Imeglimin) sales in Japan. In addition, the Company is in advanced discussions – in some cases on an exclusive basis – with several potential partners for each of its three products: Imeglimin, for several countries not covered by its agreement with Sumitomo Pharma, PXL065 and PXL770.

Based on:

- i. its cash position on June 30, 2024,
- ii. tranches already drawn<sup>3</sup> or fully available as of the date of this press release under the equity-linked financing facility with IRIS,
- iii. no research and development expenses, and
- iv. a strict control of operating expenses,

Poxel expects that its resources, including funds available to it, will be sufficient to maintain its operations and capital expenditure until completion of the current process to monetize royalties from sales of TWYMEEG<sup>®</sup> (Imeglimin) in Japan.

### **Rescheduling of the Annual General Meeting 2024**

In view of this transaction, which is key for the Company to continue its operations, and which will be taken into consideration for the closing of its social and consolidated financial statements for the year ending December 31, 2023, Poxel announces that it requested and received confirmation from the Lyon Commercial Court of the rescheduling of its Annual General Meeting, which must be held before December 31, 2024. Once its social and consolidated financial statements are approved, Poxel will inform the market and its shareholders of its new financial calendar for 2024, including the new date of the General meeting, as soon as possible.

### **Upcoming presentation and participation of the Company in an event**

#### **3<sup>rd</sup> H.C. Wainwright Kidney Conference, July 15, 2024:**

- A virtual presentation of the Company is scheduled at 4 pm CEST - French time (10 am ET, New York time) and will focus on PXL770, a novel direct activator of adenosine monophosphate-activated protein kinase (AMPK), for the treatment of autosomal dominant polycystic kidney disease (ADPKD). Thomas Kuhn, Chief Executive Officer, will be available for one-to-one interviews on the same day.

### **About Poxel SA**

Poxel is a **clinical stage biopharmaceutical company** developing **innovative treatments for chronic serious diseases with metabolic pathophysiology**, including **non-alcoholic steatohepatitis (NASH)** and rare disorders. For the treatment of NASH, **PXL065** (deuterium-stabilized *R*-pioglitazone) met its primary endpoint in a streamlined Phase 2 trial (DESTINY-1). In rare diseases, development of **PXL770**, a first-in-class direct adenosine monophosphate-activated protein kinase (AMPK) activator, is focused on the treatment of adrenoleukodystrophy (ALD) and autosomal dominant polycystic kidney disease (ADPKD). **TWYMEEG<sup>®</sup>** (Imeglimin), Poxel's first-in-class product that targets mitochondrial dysfunction, is marketed for the treatment of type 2 diabetes in Japan by Sumitomo Pharma and Poxel expects to receive royalties and sales-based payments. Poxel has a strategic partnership with Sumitomo Pharma for Imeglimin in Japan, China, and eleven other Asian countries. Listed on Euronext Paris, Poxel is headquartered in Lyon, France, and has subsidiaries in Boston, MA, and Tokyo, Japan.

For more information, please visit: [www.poxelpharma.com](http://www.poxelpharma.com)

All statements other than statements of historical fact included in this press release about future events are subject to (i) change without notice and (ii) factors beyond the Company's control. These statements may include, without limitation, any statements preceded by, followed by or including words such as "target," "believe," "expect," "aim," "intend," "may," "anticipate," "estimate," "plan," "project," "will," "can have," "likely," "should," "would," "could" and other words and terms of similar meaning or the negative thereof. Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control that could cause the Company's actual results or performance to be materially different from the expected results or performance expressed or implied by such forward-looking statements. There can be no assurance that the Company will complete any of the foregoing transactions or that it will do so on a timely basis. The Company does not endorse or is not otherwise responsible for the content of external hyperlinks referred to in this press release.

### Glossary

You will find below a list of words and/or expressions that are used in this press release or in Poxel's communication, with the aim to bring clarification and transparency:

- **Sumitomo Pharma fiscal year** runs from April to March. As an example, Fiscal Year 2023 runs from April 1, 2023, through March 31, 2024.
- **TWYMEEG<sup>®</sup> royalties:** As per the Sumitomo Pharma's agreement, Poxel is entitled to receive royalties from the sales of TWYMEEG<sup>®</sup> (Imeglimin) in Japan
  - Sumitomo Pharma communicates gross sales of TWYMEEG<sup>®</sup>, while TWYMEEG<sup>®</sup> royalties are calculated on net sales.
  - Net sales represent the amount of gross sales to which are deducted potential rebates, allowances, and costs such as prepaid freight, postage, shipping, customs duties and insurance charges.
  - Poxel is entitled to receive escalating royalties of 8-18% on TWYMEEG<sup>®</sup> net sales from Sumitomo Pharma.
- **Positive net royalties:** as part of the Merck Serono licensing agreement, Poxel will pay Merck Serono a fixed 8% royalty based on the net sales of TWYMEEG<sup>®</sup>, independent of the level of sales. All royalties that Poxel receives from TWYMEEG<sup>®</sup> net sales above that 8% level are considered as positive net royalties. Net royalties will therefore be positive for Poxel when TWYMEEG<sup>®</sup> net sales exceed JPY 5 billion in a fiscal year and royalties reach 10% and above.

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<sup>1</sup> Converted at the exchange rate on June 30, 2024

<sup>2</sup> Converted at the exchange rate on December 31, 2023

<sup>3</sup> Since March 31, 2023, 11 additional tranches have been drawn for a total amount of EUR 5.8 million.

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Source: Poxel SA