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5 May 2026



**ImmuPharma PLC  
("ImmuPharma" or the "Company")**

**ImmuPharma Initiates IND-Enabling Program for Kapiglucaagon to treat Diabetes**

ImmuPharma plc, (LSE AIM: IMM), the specialist drug discovery and development company, is pleased to announce the initiation of IND-enabling activities for its Kapiglucaagon diabetes program, following the execution of a 'Work Order' with specialist pharmaceutical consultancy tranScrip Limited ("tranScrip").

Under the agreement, tranScrip will support the development of the regulatory strategy and the preparation and execution of a pre-IND meeting with the FDA, including the preparation of an integrated briefing package and IND planning activities.

The program is expected to progress through a streamlined development pathway, with ImmuPharma evaluating a 505(b)(2) regulatory approach in the United States, leveraging existing data on native glucagon, subject to FDA confirmation.

**About Kapiglucaagon**

Kapiglucaagon is a proprietary glucagon prodrug being developed for the treatment of Type 1 diabetes (T1D), to overcome the inherent physicochemical limitations of native glucagon. The program is designed to improve solubility and formulation stability, with potential application in dual-hormone artificial pancreas systems and other glucagon-based therapeutic settings, which are expected to support the development of next-generation alternatives to current insulin-only pump devices. Through this innovation, ImmuPharma aims to contribute to next-generation diabetes care, in which artificial pancreas systems, may reduce disease burden while improving metabolic control and patient quality of life. The global Insulin Pump market is forecast to reach \$13.6bn sales by 2035 (Source: Roots Analysis).

ImmuPharma believes Kapiglucaagon represents an important strategic opportunity, alongside its lead asset, P140. ImmuPharma has previously stated that it has an accelerated development plan for Kapiglucaagon, through a 505(b)(2) regulatory pathway (described in notes) and that the program is being supported by the recently approved funding initiative, which is intended to advance the asset over the next two years.

## Next steps

Kapiglucaagon has established a strong scientific rationale and a growing body of supporting manufacturing and preclinical data, which the Company believes provides a solid foundation for further development. A key milestone in the IND-enabling process will be a pre-IND meeting with the FDA to align on the regulatory pathway and the scope of the required Chemistry, Manufacturing and Controls (CMC), preclinical and clinical program. Following this meeting, ImmuPharma intends to progress towards IND submission and, subject to regulatory alignment, first-in-human studies to support the next stage of value creation for Kapiglucaagon.

### **Dr Sébastien Goudreau, Chief Scientific Officer of ImmuPharma, said:**

*“The initiation of IND-enabling activities represents an important step in advancing Kapiglucaagon towards clinical development. By establishing a clear regulatory pathway, we aim to efficiently and cost-effectively progress the program towards first-in-human studies and position it for future partnering opportunities.”*

### **Mark Corbett, Chief Executive Officer of tranScrip, said:**

*“tranScrip is pleased to be working alongside ImmuPharma at this important stage of the Kapiglucaagon program. By combining regulatory strategy with hands-on preparation for FDA interaction, we aim to help ImmuPharma move forward with clarity, confidence and momentum toward IND-enabling milestones.”*

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## Notes to Editors

### **About ImmuPharma PLC**

ImmuPharma PLC (LSE AIM: IMM) is a specialty biopharmaceutical company that discovers and develops peptide-based therapeutics. The Company’s portfolio includes novel peptide therapeutics for autoimmune diseases and anti-infectives.

For additional information about ImmuPharma please visit [www.immupharma.co.uk](http://www.immupharma.co.uk).

ImmuPharma’s LEI (Legal Entity Identifier) code: 213800VZKGHXC7VUS895.

***Kapiglucaagon: A Stable Next-Generation Glucagon Prodrug for Diabetes***

Kapiglucagon has been developed to address the key pharmaceutical limitations associated with native glucagon. It is a water-soluble glucagon prodrug designed to maintain high stability in aqueous solution while regenerating native glucagon *in vivo* following subcutaneous administration. Unlike native glucagon, which rapidly aggregates and forms fibrils in solution, Kapiglucagon demonstrates excellent solubility and formulation stability, enabling the development of clean, saline-based formulations that do not clog pump-based delivery systems. This improved physicochemical profile makes Kapiglucagon particularly well suited for continuous or intermittent delivery in advanced diabetes technologies, including next-generation artificial pancreas systems. By combining the therapeutic activity of native glucagon with a formulation that overcomes its inherent instability, Kapiglucagon has the potential to provide more reliable and practical dual-hormone automated glucose control solutions for patients with Type 1 Diabetes and avoid the long-term health complications of inadequate blood glucose control.

ImmuPharma's vision is to position Kapiglucagon as a key enabling solution for next-generation artificial pancreas technologies. By overcoming the long-standing instability of native glucagon in aqueous formulations, Kapiglucagon offers the potential to deliver a stable, pump-compatible glucagon source, allowing dual-hormone closed-loop systems to operate safely and effectively. Through this innovation, ImmuPharma aims to contribute to a new generation of diabetes care in which artificial pancreas systems can significantly reduce the daily burden of disease while improving metabolic control and patient quality of life.

#### **About 505(b)(2) regulatory approval**

A 505(b)(2) is a U.S. FDA drug approval pathway that sits between a full NDA and a generic. The 505(b)(2) approval route allows a company to obtain approval for a modified version of an existing drug by relying partly on data which the FDA already has for the reference product, in this case a glucagon brand. The timeframe, cost and clinical study requirements for completing such a program may be considerably reduced compared to a normal NDA (new drug application) that follows a full 505(b)(1) NDA development pathway. A (PTE) Patent Term Extension of 5 years may also be applied to the existing patent life of Kapiglucagon which could result in a patent expiry extension to 2043.

Kapiglucagon has established a strong scientific rationale and a growing body of supporting CMC and preclinical data, which the Company believes provides a solid foundation for further development. The first step is expected to be a Pre-IND meeting with the FDA to align on the proposed regulatory pathway and the scope of the required CMC, preclinical and clinical program. Following this interaction, the Company intends to advance the remaining development activities, including IND-enabling work, with the objective of entering a focused clinical study designed to generate safety, pharmacokinetic and pharmacodynamic data to support the next stage of value creation for Kapiglucagon.

#### **About tranScrip**

tranScrip is a specialist pharmaceutical consultancy, delivering expert medical, clinical and regulatory solutions through a multidisciplinary team that helps transform great science into valuable medicines tranScrip gives direct access to senior specialist, hands-on drug development experts who help navigate complexity, reduce risk, maximise opportunities, and make confident decisions at critical development milestones. For more information go to: <https://transcrip-group.com/>

#### **Glossary**

CMC	Chemistry, Manufacturing and Controls
FDA	U.S. Food and Drug Administration
IND	Investigational New Drug
NDA	New Drug Application