IMPACT Therapeutics, Inc
南京英派藥業股份有限公司
(A joint stock company established in the People's Republic of China with limited liability)
(Stock Code: 7630)

VOLUNTARY ANNOUNCEMENT
POSITIVE CHMP OPINION FOR SENAPARIB, AS POTENTIAL FIRST-LINE MAINTENANCE TREATMENT OF ADVANCED EPITHELIAL OVARIAN, FALLOPIAN TUBE, AND PRIMARY PERITONEAL CANCER

This announcement is made by IMPACT Therapeutics, Inc (the "**Company**", together with its subsidiaries, the "**Group**" or "**IMPACT**") on a voluntary basis to inform the Company's shareholders and potential investors about the latest business update of the Group.

The Company is pleased to announce that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending the granting of a Marketing Authorisation (MA) for the medicinal product Sepalna® (Senaparib), intended for the maintenance treatment of advanced epithelial ovarian, fallopian tube and primary peritoneal cancer.

Following the CHMP's recommendation for approval, senaparib will be submitted to the European Commission (EC) for final decision. Once approved by the EC, senaparib will be authorized for marketing in all European Member States and European Economic Area countries.

The positive opinion from CHMP is primarily based on the results of the pivotal Phase III FLAMES study. The FLAMES study is a Phase III, randomized, double-blind, placebo-controlled, multicenter trial to evaluate the efficacy and safety of senaparib versus placebo as the maintenance treatment for subjects with advanced (FIGO Stage III-IV) epithelial high-grade Ovarian Cancer (OC), fallopian tube, and primary peritoneal cancer who are in response (complete or partial) following first-line (1L) platinum-based chemotherapy. In the FLAMES study, senaparib as 1L maintenance monotherapy reduced the risk of progression or death versus placebo in a broad patient population with advanced OC, irrespective of BRCA mutation status and with consistent benefits observed between homologous recombination subgroups. Notably, at the prespecified interim analysis, the median PFS was NR with senaparib versus 13.6 months with placebo (HR = 0.43, 95% CI 0.32-0.58; p<0.0001). Senaparib was associated with a 57% reduction in the risk of progression or death compared with placebo. The above results of the FLAMES study were published in Nature Medicine in May 2024.

Reference is made to the voluntary announcement of the Company dated July 30, 2026, in relation to the exclusive licensing agreement entered into between the Company and Pharmanovia. Under the licensing agreement, the Company has granted Pharmanovia exclusive manufacturing, development and commercialization rights for senaparib as maintenance monotherapy for advanced epithelial high-grade ovarian, fallopian tube and primary peritoneal cancer across 66 countries, including all 27 European Union member states, as well as the United Kingdom, Norway, Iceland, Switzerland, Liechtenstein, Australia, New Zealand and countries in the Middle East and North Africa.

Dr. Sui Xiong Cai, chief executive officer of our Company, commented: "The positive opinion from EMA CHMP is a critical step towards market authorization by the EC, marking a significant milestone not only for senaparib and IMPACT, but also for the global footprint of innovative Chinese-originator biotech companies. We look forward to the final decision by the EC, and we will continue to work closely with our partner Pharmanovia to efficiently advance access to senaparib across the licensed territories in Europe, the Middle East, North Africa, Australia and New Zealand, accelerating the global reach of this innovative Chinese-originated drug to benefit more patients worldwide."

Dr. Stephan Eder, chief executive officer of Pharmanovia, added: "Our partnership combines IMPACT's scientific expertise with our launch and market expertise. The CHMP's positive opinion marks an important next step in the regulatory process for this medicine. Our focus is now on using our market access, medical and launch capabilities to bring senaparib as a novel treatment option to patients in our territories."

About Senaparib (IMP4297)

Senaparib (Sepalna®) is a novel, highly potent PARP1/2 inhibitor independently developed by the Company. Its unique molecular structure ensures excellent target selectivity and a wide safety window. Senaparib capsules received National Medical Products Administration of China approval in January 2025 as a first-line maintenance therapy for adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer achieving complete or partial response to platinum-based chemotherapy, and has been subsequently included in the National Reimbursement Drug List in December 2025. The Company is actively advancing the clinical and regulatory development of senaparib globally. Its Marketing Authorisation Application in Europe was formally accepted by the EMA in August 2025. Concurrently, the Company is pursuing life cycle management for senaparib, exploring combination therapy opportunities, and expanding into multiple indications.

About Ovarian Cancer (OC)

OC is one of the most lethal malignancies affecting women, with a mortality rate that ranks among the highest for female cancers. OC patients typically receive 1L systemic therapy upon diagnosis. Following completion of initial treatment, patients who achieve complete or partial response generally enter the 1L maintenance phase as part of the standard treatment paradigm. As such, 1L maintenance therapy represents the largest and most broadly applicable treated population within the overall OC patient pool. In 2024, the targeted patient population for OC 1L maintenance therapy was 182.0 thousand globally and 41.7 thousand in China. The global and China OC drug markets have experienced rapid growth and are expected to continue expanding strongly through 2033, driven primarily by 1L maintenance therapy and later-line BRCAmut treatments, with 1L maintenance accounting for the largest share of market demand.

About Pharmanovia

Pharmanovia is a global specialty pharmaceutical company. Pharmanovia partners with innovative biotech and large pharma to bring innovative specialty medicines to patients, while supporting trusted established brands across more than 160 markets.

About IMPACT

Founded in 2009, we are a commercial-stage biotechnology company focused on advancing synthetic lethality (SL)-based precision anti-cancer therapies globally, delivering innovative treatments to address the unmet medical needs of cancer patients. IMPACT was successfully listed on the Main Board of The Stock Exchange of Hong Kong Limited on May 13, 2026 (Stock Code: 07630.HK). We have in-house discovered and developed one of the most comprehensive and advanced SL franchises and are one of only three companies with both commercial-stage PARP1/2 inhibitors and clinical-stage next-generation PARP1-selective inhibitors worldwide.

Our core product, senaparib (IMP4297), has already been commercialized, following its approval as 1L maintenance therapy for OC "all-comers" in China in January 2025, and is reimbursable for OC 1L "all-comers" since January 1, 2026. Senaparib also delivered the most favorable PFS outcome among PARP1/2 inhibitors (non head-to-head) for 1L maintenance therapy for OC "all-comers" in China, setting a new benchmark in this class.

Our major pipeline assets include the PARP1/2 inhibitor senaparib (IMP4297), PARP1-selective inhibitors (IMP1734 and IMP1707, co-developed with Eikon Therapeutics), ATR inhibitor (IMP9064), WEE1 inhibitor (IMP7068), and multiple other synthetic lethality target inhibitors.

Our continued growth is powered by an integrated R&D platform that enables innovation across both small molecules and emerging modalities, including ADCs and degraders, with the identification of PCC from each modality. Additionally, we have forged partnerships with leading global biotech and China pharmaceutical companies to date, as validation of our pipeline and R&D platform.

Cautionary Statement required by Rule 18A.05 of the Listing Rules: The Company cannot guarantee that senaparib will be successfully developed or ultimately marketed in the licensed territories. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By order of the Board
IMPACT Therapeutics, Inc
南京英派藥業股份有限公司
Dr. Sui Xiong CAI
Executive Director and Chief Executive Officer

Hong Kong, September 18, 2026

As at the date of this announcement, the board of directors of the Company comprises (i) Dr. Sui Xiong CAI, Dr. Ye Edward TIAN and Ms. Ning MA as executive Directors; (ii) Dr. Cong XU, Dr. Qiang XU and Mr. Tao LIU as non-executive Directors; and (iii) Dr. Edward Ming GUO, Mr. Chi Hung SIU and Dr. Liming SHAO as independent non-executive Directors.