

GSK and iTeos Therapeutics announce development and commercialisation collaboration for EOS-448, an anti-TIGIT monoclonal antibody, enabling novel next-generation immuno-oncology combinations

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BY [GSK](#)

For media and investors only

- EOS-448 is currently in phase I for advanced solid tumours with a randomised PD-1 combination study planned for 2022
- iTeos to receive a \$625 million upfront payment in addition to potential milestones, and royalty payments on ex-US sales
- GSK and iTeos will co-commercialise and share profits in the US
- GSK now has the leading portfolio of antibodies targeting the CD226 axis - a key target for next-generation immuno-oncology therapies

GlaxoSmithKline plc (LSE/NYSE: GSK) and iTeos Therapeutics (NASDAQ: ITOS) today announced an agreement to co-develop and co-commercialise EOS-448, an anti-TIGIT monoclonal antibody currently in phase I development as a potential treatment for patients with cancer. TIGIT, part of the CD226 checkpoint axis, has demonstrated potential as a promising target for the next generation of immuno-oncology therapies based on compelling preclinical data and a phase II randomised clinical trial. With this collaboration GSK is uniquely positioned with access to antibodies that synergistically target all three known CD226 checkpoints - TIGIT, CD96 and PVRIG.

Dr Hal Barron, Chief Scientific Officer and President R&D, GSK, said:

Immuno-oncology has transformed cancer care but unfortunately less than 30 percent of patients respond to treatment with the current leading immune checkpoint inhibitors. Based on the underlying science, we believe that combinations of a PD-1, TIGIT, CD96 and PVRIG inhibitor could become transformative medicines for many patients with cancer. We are excited to collaborate with the team at iTeos and together we can play a leading role in the next generation of immuno-oncology therapies.

Since GSK validated the role of CD226 axis targets as important in oncology, it has been strategically building a carefully constructed set of assets to target this network of checkpoint inhibitors. The addition of EOS-448 results in GSK being the only company with antibodies targeting all three known checkpoints – TIGIT (via EOS-448), CD96 (via GSK'608), and PVRIG (via GSK'562). Together with GSK's recently approved anti-PD-1, Jemperli (dostarlimab), this comprehensive portfolio of potential next generation immuno-oncology agents will be explored through various novel combinations, including doublets and triplets, to evaluate their potential to transform treatment options for patients with multiple different cancers.

Michel Detheux, President and CEO, iTeos, said:

Through this transformative collaboration, iTeos now has access to GSK's best-in-class resources which will provide us with a significant advantage in a highly competitive, global market. We have chosen GSK because of their commercial capabilities, experience in immuno-oncology and their commitment to invest in the rapid advancement of our TIGIT programme and create a clear path forward for EOS-448. Inspired by the multifaceted mechanism of action of EOS-448 and promising early results in clinical trials, this collaboration allows us to accelerate and expand the clinical development of EOS-448. We are more confident than ever in our ability to succeed. This collaboration validates our science and provides a catalyst for the future of iTeos. The collaboration with GSK will allow our team to continue to develop next generation immunotherapies starting with inupadenant, our highly differentiated clinical-stage A2A adenosine receptor antagonist, and to drive scientific innovation with our expertise in tumour immunology to build our pipeline.

EOS-448 is currently in an open-label phase I study in patients with advanced solid tumours. GSK and iTeos plan to start combination studies of EOS-448 with dostarlimab in 2022. GSK'608 (anti-CD96 being developed in collaboration with 23andMe) is in phase I as monotherapy and in combination with dostarlimab. GSK expects to submit an Investigational New Drug application for GSK'562 (anti-PVRIG in-licensed as SRF-813 from Surface Oncology) by mid-2022.

Under the terms of the collaboration agreement, iTeos will receive an upfront payment of \$625 million. iTeos will be eligible to receive up to an additional \$1.45 billion in milestone payments, should the EOS-448 programme achieve certain development and commercial milestones.

Within the collaboration, GSK and iTeos will share responsibility and costs for the global development of EOS-448 and will jointly commercialise and equally split profits in the US. Outside of the US, GSK will receive an exclusive license for commercialisation and iTeos will receive tiered royalty payments.

The collaboration agreement is conditional upon customary conditions including review by the appropriate regulatory agencies under the Hart-Scott-Rodino Act.

iTeos will host a conference call to discuss the agreement today, Monday, June 14 at 8:30 a.m. ET. Details are as follows:

Participant Dial-In: (833) 607-1661

International Dial-In: (914) 987-7874

Webcast: <https://edge.media-server.com/mmc/p/xz7hasbz>

The live audio webcast will also be accessible from the Events page of the Company's IR website at <https://investors.iteotherapeutics.com/news-and-events/events>. A replay will be available on the Company's website approximately two hours after completion of the event and for 30 days following the call.

GSK is focused on maximising patient survival through transformational medicines. GSK's pipeline is focused on immuno-oncology, cell therapy, cancer epigenetics and synthetic lethality. Our goal is to achieve a sustainable flow of new treatments based on a diversified portfolio of investigational medicines utilising modalities

such as small molecules, antibodies, antibody drug conjugates and cells, either alone or in combination.

GSK is a science-led global healthcare company. For further information please visit www.gsk.com/about-us.

EOS-448 is a monoclonal human IgG1 antibody designed to bind with high affinity TIGIT, a negative co-stimulatory immune checkpoint expressed T cells and NK cells. EOS-448 potently triggers an antitumor response by the immune system via a multi-faceted mechanism. By binding to TIGIT, EOS-448 blocks its interaction with TIGIT ligands including CD155 and CD112, which can then bind to CD226 and activate immune response of T cells and NK cells. In addition, IgG1 binds to FcγR to trigger pro-inflammatory cytokine release, activation of antigen presenting cells and depletion of TIGIT+ Tregs and exhausted T cells. In a phase 1 dose escalation, presented at AACR 2021, EOS-448 showed a favorable tolerability profile and early signs of clinical activity in advanced cancers with one confirmed partial response and 9 stable diseases out of 20 evaluable patients with advanced, difficult to treat cancers. Depletion of TIGIT+ suppressive and exhausted cells were shown at even the lowest tested dose thereby providing evidence of engagement of the FcγR, and the potential of EOS-448 to activate multiple immune mechanisms. This program was funded by a SPW/EER grant.

About iTeos Therapeutics, Inc.

iTeos Therapeutics is a clinical-stage biopharmaceutical company pioneering the discovery and development of a new generation of highly differentiated immuno-oncology therapeutics for patients. The Company's innovative pipeline includes two clinical-stage programs targeting novel, validated immuno-oncology. The initial antibody product candidate, EOS-448, is a high affinity, potent, anti-TIGIT antibody with a functional Fc domain, designed to enhance the anti-tumor response through a multifaceted immune modulatory mechanism. An open-label Phase 1 clinical trial of EOS-448 is ongoing in adult cancer patients with advanced solid tumors with preliminary data indicating preliminary clinical activity as a monotherapy and a favorable tolerability profile. The Company is also advancing inupadenant, a first insurmountable adenosine A2A receptor antagonist in clinical development tailored to overcome cancer immunosuppression. iTeos is conducting an open-label multi-

arm Phase 1/2a clinical trial of inupadenant in adult cancer patients with advanced solid tumors. Preliminary results indicate encouraging single-agent activity as well as the identification of a potential predictive biomarker. iTeos Therapeutics is headquartered in Cambridge, MA with a research center in Gosselies, Belgium.

iTeos Therapeutics, Inc. Forward-Looking Statements

This press release contains forward-looking statements and information within the meaning of The Private Securities Litigation Reform Act of 1995 and other federal securities laws. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will," "intends," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include but are not limited to statements regarding the closing of the transaction; iTeos' right to receive any upfront payment, milestones and royalty payments from GSK pursuant to the agreement and GSK's obligation to share responsibility and costs for the global development of EOS-448; EOS-448's potential as a promising target for the next generation of immuno-oncology therapies; the potential of combinations of TIGIT, CD96 and PVRIG to become transformative medicines for many patients with cancer; GSK's best-in-class resources providing iTeos with a significant advantage in a highly competitive global market; the potential of the collaboration with GSK to accelerate and expand the clinical development of EOS-448; iTeos' plan to continue to develop next generation immunotherapies starting with inupadenant; and GSK and iTeos' plan to start combination studies of EOS-448 with dostarlimab in 2022.

These forward-looking statements involve risks and uncertainties that may cause actual results to differ materially from those expressed or implied in the forward-looking statements. Many of these risks and uncertainties are beyond iTeos' control. Known risk factors include, among others, market conditions, the expected benefits and opportunities related to the agreement between iTeos and GSK may not be realized or may take longer to realize than expected due to a variety of reasons, including any inability of the parties to perform their commitments and obligations under the agreement, challenges and uncertainties inherent in product research and development and manufacturing limitations; success in preclinical testing and early

clinical trials does not ensure that later clinical trials will be successful, and early results from a clinical trial do not necessarily predict final results; the data for EOS-448 may not be sufficient for obtaining regulatory approval; iTeos may not be able to execute on its business plans, including meeting its expected or planned regulatory milestones and timelines, research and clinical development plans, and bringing its product candidates to market, for various reasons, some of which may be outside of iTeos' control, including possible limitations of company financial and other resources, manufacturing limitations that may not be anticipated or resolved for in a timely manner, regulatory, court or agency decisions such as decisions by the United States Patent and Trademark Office with respect to patents that cover our product candidates and the impact of the COVID-19 pandemic; and those risks identified under the heading "Risk Factors" in iTeos's most recent Annual Report on Form 10-K for the year ended December 31, 2020 and most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) as well as other SEC filings made by the Company which you are encouraged to review.

Any of the foregoing risks could materially and adversely affect the Company's business, results of operations and the trading price of iTeos' common stock. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. iTeos does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.

Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the Company's Annual Report on Form 20-F for 2020 and any impacts of the COVID-19 pandemic.

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