ITM and Clovis Oncology Announce Lutetium-177 Clinical Supply Agreement

ITM to supply its medical radioisotope, no-carrier-added Lutetium-177, for the clinical development of Clovis Oncology's Targeted Radionuclide Therapy candidate FAP-2286

Munich, Germany and BOULDER, Colo., 19 October, 2021 – ITM Isotope Technologies Munich SE, a leading radiopharmaceutical biotech company, and Clovis Oncology, Inc. (NASDAQ: CLVS) today announced the signing of a clinical supply agreement that provides Clovis Oncology with ITM's therapeutic radioisotope no-carrier-added Lutetium-177 (n.c.a. ^{177}Lu), EndolucinBeta®, for use in the clinical development of FAP-2286, Clovis' fibroblast activation protein (FAP)-targeting therapeutic candidate. FAP-2286 is the first peptide-targeted radionuclide therapeutic (PTRT) candidate directed against fibroblast activation protein undergoing clinical testing and is currently being investigated in the Phase 1/2 LuMIERE study for patients with advanced solid tumors. The agreement covers an initial period of five years. Further details of the agreement were not disclosed.

"This agreement underscores the potential of our n.c.a. Lutetium-177 to provide therapeutic value to patients with hard-to-treat tumors. Through our proprietary pipeline of Targeted Radionuclide Therapies and our agreements with other oncology leaders, we are establishing a new era of precision oncology treatments and we are happy to contribute to this exciting Clovis program," commented Steffen Schuster, CEO of ITM.

"Clovis Oncology is committed to advancing FAP-2286's clinical development program and emerging as a leader in targeted radionuclide therapy. A critical element to advance this program is ensuring long-term supply of radioisotopes, and this agreement allows us to achieve that goal," said Patrick Mahaffy, President and CEO of Clovis Oncology. "*In particular, we value ITM's radiopharmaceutical expertise and global reach as we advance our targeted radionuclide therapy program into the clinic."*

FAP-2286 is a clinical candidate under investigation as a peptide-targeted radionuclide therapy (PTRT) and imaging agent targeting FAP. FAP is highly expressed by cancer-associated fibroblasts (CAFs), which are found in the majority of cancer types, but with limited expression in healthy fibroblasts, potentially making it a suitable target across a wide range of tumors. FAP-2286 consists of two functional elements; a targeting peptide that binds to FAP and a site that can be used to attach medical radioisotopes, such as Lutetium-177 for therapeutic use, or Gallium-68 for imaging use.

ITM's n.c.a. ^{177}Lu (EndolucinBeta®) is a high-purity version of the beta-emitting radioisotope Lutetium-177, that can be linked to a variety of tumor-specific targeting molecules for Targeted Radionuclide Therapy and has demonstrated significant anti-tumor effects in clinical and commercial use. ITM has developed a unique methodology to produce the highly pure form of Lutetium-177, without metastable Lutetium-177m, and manufactures n.c.a. ^{177}Lu for development partnerships, distribution to clinics worldwide, and its own growing precision oncology pipeline.

In June 2021, Clovis initiated the Phase 1/2 LuMIERE clinical study of FAP-2286 in advanced solid tumors. The Phase 1 portion of the LuMIERE study (NCT 04939610) will evaluate the safety of the FAP-targeting investigational therapeutic agent and identify the recommended Phase 2 dose and schedule of Lutetium-177 labeled FAP-2286 (^{177}Lu-FAP-2286), for which ITM will provide its n.c.a. ^{177}Lu. Once the Phase 2 dose is determined, Phase 2 expansion cohorts are planned in multiple tumor types.

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About FAP-2286

FAP-2286 is a clinical candidate under investigation as a peptide-targeted radionuclide therapy (PTRT) and imaging agent targeting fibroblast activation protein (FAP). FAP-2286 consists of two functional elements; a targeting peptide that binds to FAP and a site that can be used to attach radioactive isotopes for imaging and therapeutic use. High FAP expression has been shown in pancreatic ductal adenocarcinoma, cancer of unknown primary, salivary gland, mesothelioma, colon, bladder, sarcoma, squamous non–small cell lung, and squamous head and neck cancers. High FAP expression was detected in both primary and metastatic tumor samples and was independent of tumor stage or grade. Clovis holds US and global rights for FAP-2286 excluding Europe, Russia, Turkey, and Israel.

FAP-2286 is an unlicensed medical product. For more information about FAP-2286, Targeted Radionuclide Therapy (TRT), or Clovis' TRT development program, please visit www.targetedradiotherapy.com.

About n.c.a. Lutetium-177 / EndolucinBeta®

No carrier-added Lutetium-177 (n.c.a. ^{177}Lu) chloride, is a radiopharmaceutical precursor used in Targeted Radionuclide Therapy for the treatment of various diseases, like cancer. When labeled with a tumor-specific targeting molecule (e. g. peptide or antibody), the targeted radiopharmaceutical binds to a tumor-specific receptor, according to the lock and key principle. N.c.a. ^{177}Lu has a half-life of 6.647 days and provides the highest specific activity of more than 3,000 GBq/mg at Activity Reference Time (ART). Optimal preconditions for efficient radiolabeling of biomolecules over its entire shelf-life of 9 days after production are ensured. N.c.a. ^{177}Lu exhibits an extraordinary level of radionuclidic purity and does not contain metastable Lutetium-177m circumventing cost intensive clinical disposal management.

About Targeted Radionuclide Therapy

Targeted Radionuclide Therapy is an emerging class of cancer therapeutics, which seeks to deliver radiation directly to the tumor while minimizing delivery of radiation to normal tissue. Targeted radionuclide therapies are created by linking radioactive isotopes, also known as radionuclides, to targeting molecules (e.g., peptides, antibodies, small molecules) that can bind specifically to tumor cells or other cells in the tumor environment. Based on the radioactive isotope selected, the resulting agent can be used to image and/or treat certain types of cancer. Agents that can be adapted for both therapeutic and imaging use are known as "theranostics." Clovis, together with licensing partner 3B Pharmaceuticals, is developing a pipeline of novel, targeted radiotherapies for cancer treatment and imaging, including its lead candidate, FAP-2286, an investigational peptide-targeted radionuclide therapeutic (PTRT) and imaging agent, as well as three additional discovery-stage compounds. ITM is developing a proprietary precision oncology pipeline of targeted radiopharmaceuticals for diagnostics and treatment of a range of hard-to-treat cancer indications, such as neuroendocrine tumors, prostate cancer, glioblastoma, osteosarcoma and bone metastases, as well as folate receptor α positive tumors like lung, ovarian or breast cancer. Additionally, ITM supplies partners with its high-purity n.c.a. ^{177}Lu for clinical and commercial development.

About ITM Isotope Technologies Munich SE

ITM, a privately held radiopharmaceutical biotech company founded in 2004, is dedicated to providing the most precise cancer radiotherapeutics and diagnostics to meet the needs of patients, clinicians and our partners through excellence in development, production and global supply. With patient benefit as the driving principle for all we do, ITM is advancing a broad pipeline combining its high-quality radioisotopes with targeting molecules to develop precision oncology treatments. ITM is leveraging its leadership and nearly two decades of radioisotope expertise combined with its worldwide network to enable nuclear medicine to reach its full potential for helping patients live longer and better. For more information, please visit www.itm-radiopharma.com.

About Clovis Oncology

Clovis Oncology, Inc. is a biopharmaceutical company focused on acquiring, developing, and commercializing innovative anti-cancer agents in the US, Europe, and additional international markets. Clovis Oncology targets development programs at specific subsets of cancer populations, and simultaneously develops with partners diagnostic tools intended to direct a compound in development to the population that is most likely to benefit from its use. Clovis Oncology is headquartered in Boulder, Colorado; please visit www.clovisoncology.com for more information, including additional office locations in the US and Europe.

ITM Corporate Contact
Julia Hofmann, Head of Corporate Communications
Susanne Karlsson, Deputy Head of Corporate Communications
Phone: +49 89 329 8986 1502
Email: communications@itm-radiopharma.com

ITM Media Requests
Trophic Communications
Stephanie May or Valeria Fisher
Phone: +49 171 185 56 82
Email: itm@trophic.eu

Clovis Investor Contacts
Anna Sussman, +1 303.625.5022
asussman@clovisoncology.com
or
Breanna Burkart, +1 303.625.5023
bburkart@clovisoncology.com

Clovis Media Contacts
US
Lisa Guiterman, 301.347.7964
clovismedia@clovisoncology.com
Europe
Jake Davis, +44 (0) 203.946.3538
Jake.Davis@publicisresolute.com

Clovis Disclaimer

To the extent that statements contained in this press release are not descriptions of historical facts regarding Clovis Oncology, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Examples of forward-looking statements contained in this press release include, among others, statements of our intentions and expectations for our development and discovery programs, including the timing and pace of pre-clinical development, plans for clinical development, plans for additional applications of the FAP-2286 peptide, including potential indications, tumor types and combination trials, and regulatory plans with respect to FAP-2286. Such forward-looking statements involve substantial risks and uncertainties that could cause Clovis Oncology's actual results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in drug discovery and pre-clinical and clinical development, including the outcome of pre-clinical studies and clinical trials, whether initial results, findings or research will support future studies or development, whether future study results will be consistent with previous study findings or other results, including pre-clinical studies, results in named-patient or similar programs or clinical trials, whether additional studies not originally contemplated are determined to be necessary, the timing of initiation, enrollment and completion of planned studies and actions by the FDA, the EMA or other regulatory authorities regarding data required to support drug applications and whether to approve drug applications. Clovis Oncology undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the company in general, see Clovis Oncology's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and its other reports filed with the Securities and Exchange Commission.