MolMed enters an agreement with GSK for the manufacture of the experimental gene therapy for compassionate use for ADA-SCID

Milan (Italy), 22 November 2013 – MolMed S.p.A. (MLM.MI) announces that it has entered into an agreement with GlaxoSmithKline (GSK) under which MolMed will be responsible for the manufacture of GSK’s investigational gene therapy for compassionate use in patients with Adenosine Deaminase Deficiency – Severe Combined Immune Deficiency (ADA-SCID) in the potential event that an investigator led named patient compassionate use application is approved.

ADA-SCID is a rare and severe form of immune-deficiency, affecting approximately 350 children worldwide, caused by the alteration of a single gene coding for the adenosine deaminase enzyme (ADA). In these patients, the immune system is so severely impaired that it is unable to defend against infectious agents.

MolMed previously produced on behalf of Telethon the investigational gene therapy where the correct form of the ADA gene is inserted into the patients’ own bone marrow derived stem cells. GSK is now continuing the clinical development of the ADA-SCID gene therapy in collaboration with the San Raffaele Telethon Institute for Gene Therapy (HSR-TIGET) from which GSK has in-licensed the rights to develop and commercialize the therapy.

Clinical trials testing the gene therapy are now complete and for patients lacking suitable therapy referred to San Raffaele Hospital, following ethical approval, GSK will support compassionate use named patient through product manufacture at MolMed.

Claudio Bordignon, chairman and CEO of MolMed, comments: “This new agreement with GSK on the one hand supports the technological-scientific and industrial excellence of MolMed, reinforcing the Company’s leadership in the Gene and Cell Therapy field, and, on the other hand, demonstrates our ability to build and strengthen the business partnership with a major pharmaceutical group worldwide.”

Under the original agreement announced by MolMed in August 2011, MolMed developed the production process for the investigational gene therapy for ADA-SCID.

About MolMed’s activity area: “GMP Solutions”

MolMed has key expertise in cell and gene therapy: its service area, “GMP Solutions”, provides tailor-made services for cell and gene therapy projects, offering top-level expertise to develop, conduct and validate studies, from preclinical to Phase III trials, devising innovative testing procedures and addressing the unique test specifications required for novel cell-based therapeutics. MolMed’s development, manufacturing and clinical expertise in ex vivo cell and gene therapy includes scale-up and cGMP (current Good Manufacturing Practices) production of clinical-grade viral vectors, and manufacturing of patient-specific genetically engineered cells.

This press release is written in compliance with public disclosure obligations established by CONSOB (Italian securities & exchange commission) resolution no. 11971 of 14 May 1999, as subsequently amended.
About MolMed

MolMed S.p.A. is a biotechnology company focused on research, development and clinical validation of novel anticancer therapies. MolMed's pipeline includes two antitumour therapeutics in clinical development: TK, a cell-based therapy enabling bone marrow transplants from partially compatible donors, in absence of post-transplant immune-suppression, in Phase III in high-risk acute leukaemia; NGR-hTNF, a novel vascular targeting agent, in Phase III in malignant pleural mesothelioma and in Phase II in six more indications: colorectal, lung (small-cell and non-small-cell), liver and ovarian cancer, and soft tissue sarcomas. MolMed also offers top-level expertise in cell and gene therapy to third parties to develop, conduct and validate projects from preclinical to Phase III trials, including scale-up and cGMP production of clinical-grade viral vectors, and manufacturing of patient-specific genetically engineered cells. MolMed is headquartered at the San Raffaele Biomedical Science Park in Milan, Italy. The Company's shares are listed on the main market (MTA) of the Milan Stock Exchange. (Ticker Reuters: MLMD.MI)

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