



Press Release

t2cure First Company to Have Quality of Cellular Therapeutic Certified by EMA

Frankfurt, Germany, May 25, 2010 – t2cure GmbH, a biopharmaceutical company developing and marketing stem cell-based regenerative therapies, announced today that the quality of its lead product t2c001 has been certified by the European Medicines Agency (EMA).

t2c001 is the first product ever to obtain a certificate under the EMA regulations for Advanced Therapy Medicinal Products (ATMPs). It is a somatic cell therapy product derived from autologous bone marrow, that is currently developed for the treatment of cardiovascular diseases. ATMPs are advanced biotechnology products based on cell therapy, gene therapy, or tissue engineering.

“We are absolutely excited that our lead product has been confirmed to meet the rigorous quality requirements set by the EMA, the regulatory body that will decide on a future European market approval for our product”, commented Dr Petra Rueck, CEO of t2cure.

“Together with upcoming 5-year efficacy and safety data from our Phase II trial, the EMA Certification shows that we are on the right track to bring this groundbreaking therapy closer to the market, and to patients.”

Rueck continued: “This achievement also proves that the regulations set out by the EMA for advanced therapy products and the expertise brought together by the EMA’s Committee for Advanced Therapies effectively assist small and medium-sized companies in developing advanced therapy products. These products offer novel treatment opportunities for patients who suffer from diseases, including orphan diseases, for which there are limited or no treatment options.”

ATMPs and European Regulation on ATMPs

Advanced therapy medicinal products (ATMPs) based on cell therapy, gene therapy, or tissue engineering are at the forefront of biotechnology and medical innovation. Because of their novelty and complexity, evaluating the quality, safety, and efficacy of ATMPs often

requires the development of alternative approaches that go beyond what is needed for conventional medicines. For example, testing the stability of a cell therapy product containing living cells derived from the patient's body requires a fundamentally different methodology from testing traditional pharmaceuticals.

In response to these challenges the European Regulation 1394/2007 provided a consolidated framework for this innovative class of products, including a procedure allowing small and medium-sized companies to voluntarily apply for the Certification of the pharmaceutical quality and the pre-clinical data of an advanced therapy product.

While the Certification procedure is independent from a Marketing Authorization Application (MAA), it follows the scientific and technical requirements necessary to facilitate a future MAA. The Certification confirms that the data submitted for an ATMP meet the same scientific and technical standards that apply to current regulation of other pharmaceutical and biotechnology products, including among others requirements regarding GMP, GCP, and stability.

A Certificate issued by the European Medicine Agency (EMA) is based on the evaluation by the members of its Committee for Advanced Therapies (CAT). The CAT is a multidisciplinary committee bringing together several of the best available European experts to assess the quality, safety, and efficacy of advanced therapy products.

For more information on the European ATMP regulation, including on CAT members and on the Certification procedure, see www.ema.europa.eu/htmls/human/advanced_therapies/intro

About t2cure GmbH

t2cure GmbH is a biopharmaceutical company engaged in the field of stem cell-based regenerative medicine. It develops and markets autologous bone marrow-derived progenitor cells as regenerative therapeutics for cardiovascular diseases including ischemic heart disease (acute myocardial infarction and chronic ischemic heart disease), non-ischemic heart failure and peripheral arterial disease. The most advanced project (t2c001-AMI) has successfully passed Phase II of clinical development and is commercially available to treat patients in Germany.

t2cure is privately financed by Entrepreneurs Fund and Kreditanstalt fuer Wiederaufbau.

For more information on the Company, visit our website www.t2cure.com

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