TiGenix

REGULATED INFORMATION
APRIL 22, 2013

TiGenix reports positive Phase IIa study results in refractory rheumatoid arthritis with allogeneic stem cell product Cx611

Management will conduct a conference call to discuss the results today at 4pm CET, 10am EST
Dial-in numbers are provided at the end of this press release

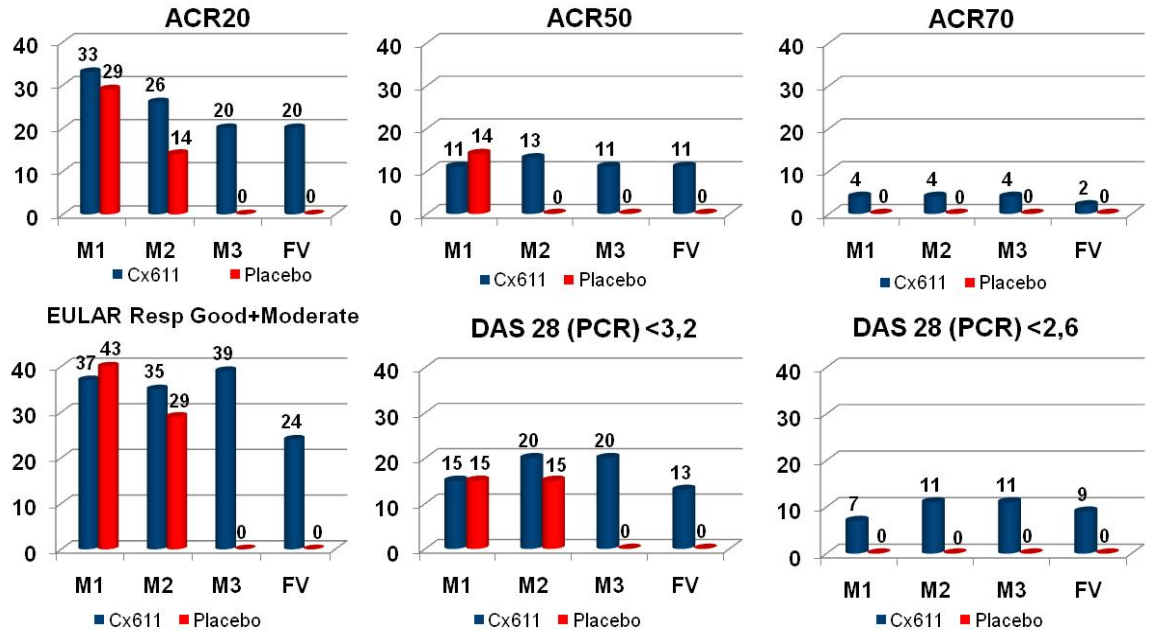
Leuven (BELGIUM) – April 22, 2013 – TiGenix (NYSE Euronext: TIG), the European leader in cell therapy, today announced positive 6-month safety data of its Phase IIa study of Cx611 in rheumatoid arthritis (RA), as well as a first indication of therapeutic activity on standard outcome measures and biologic markers of inflammation for at least three months after dosing.

The multicenter, randomized, double blind, placebo-controlled Phase IIa trial enrolled 53 patients with active refractory rheumatoid arthritis (mean time since diagnosis 15 years), who failed to respond to at least two biologics (mean previous treatment with 3 or more disease-modifying antirheumatic drugs and 3 or more biologics). The study design was based on a three-cohort dose-escalating protocol. For both the low and medium dose regimens 20 patients received active treatment versus 3 patients on placebo; for the high dose regimen 6 patients received active treatment versus 1 on placebo. Patients were dosed at day 1, 8, and 15 and were followed up monthly over a six-month period. Follow-up consisted of a detailed monthly workup of all patients measuring all pre-defined parameters. The aim was to evaluate the safety, tolerability and optimal dosing over the full 6 months of the trial, as well as exploring therapeutic activity.

Only one patient suffered serious adverse events that led to discontinuation of the treatment. All other side effects were mild and transient. Importantly, the first results show no signs of hematological side effects or thrombosis.

Measured clinical activity scores were ACR20[(1)], ACR50[(1)], ACR70[(1)], EULAR[(2)] response rates, and the disease activity score DAS28[(3)]. To gain a first insight into the therapeutic activity, these parameters were evaluated every month for six months. The below tables reflect cumulated results in percentages of all three active treatment arms at months 1 (M1), 2 (M2), 3 (M3), and “final visit” (FV). A more detailed analysis is currently ongoing.

For all graphs, N=46 for Cx611 and N=7 for placebo.



"This Phase IIa cell therapy trial is a landmark study that gives us a first indication of the potential of cell therapy in rheumatoid arthritis. The positive safety results combined with a new mechanism of action are promising, and warrant further clinical investigation," said Dr. José María Álvaro-Gracia, MD, PhD, Head of the Biological Therapies Unit at the Hospital Universitario de La Princesa, Madrid, Spain, and Principal Investigator of the study.

"We are delighted to report the positive outcome of our Phase IIa trial with Cx611 in RA," said Eduardo Bravo, CEO of TiGenix. "These results are remarkable, as they constitute the first ever signal of clinical activity of a cell therapy in RA. Moreover, this was achieved in the probably most refractory RA patient population ever evaluated in clinical studies. At the same time the outcome of the study provides unique clinical and laboratory insights to set the stage for further exploration of our eASC platform in RA and in other autoimmune and inflammatory diseases with high unmet medical needs."

About Cx611
Cx611 is a suspension of expanded allogeneic adult stem cells derived from human adipose (fat) tissue (expanded Adipose derived Stem Cells or 'eASCs') that is delivered through intravenous injection for the treatment of rheumatoid arthritis.

About rheumatoid arthritis (RA) therapy with biologics
First-line biologics have significantly improved the therapeutic options in RA. However, in more than 50% of the diagnosed and treated RA patients, subsequent biologics are currently prescribed due to inadequate response or adverse events. Ultimately, it is estimated that up to 5-10% of RA patients at some point in time will have failed most available biologics. For the US, EU and Japan alone this concerns a patient population of 150.000-300.000 patients that is in urgent need for a safe and efficacious rescue treatment.

Table legend
(1) ACR 20 means a 20% improvement in tender or swollen joint counts as well as 20% improvement in at least three of the following five criteria: patient assessment, physician assessment, erythrocyte sedimentation rate, pain scale and functional questionnaire. The ACR50 and ACR70 categories adhere to the same criteria, but for 50% and 70% improvement, respectively.
(2) EULAR, European League Against Rheumatism
(3) DAS28, Disease Activity Score 28 joint count

Conference call at 4pm CET/10am EST:

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About TiGenix

TiGenix NV (NYSE Euronext Brussels: TIG) is a leading European cell therapy company with a marketed product for cartilage repair, ChondroCelect®, and a strong pipeline with clinical stage allogeneic adult stem cell programs for the treatment of autoimmune and inflammatory diseases. TiGenix is based out of Leuven (Belgium) and has operations in Madrid (Spain), and Sittard-Geleen (the Netherlands). For more information please visit www.tigenix.com.

Forward-looking information

This document may contain forward-looking statements and estimates with respect to the anticipated future performance of TiGenix and the market in which it operates. Certain of these statements, forecasts and estimates can be recognised by the use of words such as, without limitation, "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will" and "continue" and similar expressions. They include all matters that are not historical facts. Such statements, forecasts and estimates are based on various assumptions and assessments of known and unknown risks, uncertainties and other factors, which were deemed reasonable when made but may or may not prove to be correct. Actual events are difficult to predict and may depend upon factors that are beyond TiGenix' control. Therefore, actual results, the financial condition, performance or achievements of TiGenix, or industry results, may turn out to be materially different from any future results, performance or achievements expressed or implied by such statements, forecasts and estimates. Given these uncertainties, no representations are made as to the accuracy or fairness of such forward-looking statements, forecasts and estimates. Furthermore, forward-looking statements, forecasts and estimates only speak as of the date of the publication of this document. TiGenix disclaims any obligation to update any such forward-looking statement, forecast or estimates to reflect any change in TiGenix' expectations with regard thereto, or any change in events, conditions or circumstances on which any such statement, forecast or estimate is based, except to the extent required by Belgian law.