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Subject: News von RepliCel

Posted by [Karnis](#) on Mon, 04 Feb 2013 14:52:51 GMT

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Es wird wohl die 2.Studienphase noch in diesem Jahr hier in Deutschland geben. Man darf gespannt sein...

Zum Text:

In November, RepliCel's scientific team had its first meeting with experts from the PEI to discuss important improvements to its current Good Manufacturing Practice(cGMP)-compliant manufacturing process for RCH-01. Tomorrow's meeting will address updates made to the manufacturing process that were recommended at the last PEI meeting, as well as plans the Company has to conduct a Phase II clinical trial in Germany. This study is designed to confirm the efficacy of injections of RCH-01 in over 100 male participants. In addition to augmenting the Company's information on the safety of injections of RCH-01, the trial will also provide insight into the optimal treatment regimen to increase hair growth.

"We are happy with the progress made with the design of our upcoming Phase II trial and are quite eager to get input from the PEI that will allow us to conduct the best clinical trial for the development of our product," stated Darrell Panich, Vice-President of Clinical Affairs. "Designing a trial in consultation with the PEI will facilitate the completion of the formal clinical trial application for our upcoming trial." The Company anticipates initiation of the Phase II study this year.

"The Company has made significant advancements in its manufacturing procedures and these improvements are expected to have a meaningful impact on our RCH-01 program," commented David Hall, CEO. "We are committed to receiving guidance and implementing the recommendations provided by the regulatory authorities to ensure we have a well-constructed Phase II trial that will lead to the optimum dose to treat pattern baldness. Our proposed Phase II dosing trial will provide us with 288 data points as compared to 16 in our Phase I safety trial. This should allow us to isolate an effective treatment regime," concluded Mr. Hall.

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