

# Girindus Wins Contract for Process Validation of an Oligonucleotide Orphan Drug

Bergisch Gladbach / Cincinnati, July 5, 2010. Girindus announced today that it has won a contract to begin work on validation of a manufacturing process for an oligonucleotide product currently in Phase III clinical trials. The product is a single strand phosphorothioate compound, which has received Orphan Drug designation and is destined for fast-track development.

This is the second process validation program to be initiated by Girindus in 2010, following a program begun in January for a small molecule product being developed for an in vivo imaging application. Both validation projects are being carried out at the FDA-inspected facility of Girindus America Inc. in Cincinnati, Ohio.

Commenting on these achievements, Martin Weiland, Speaker of the Management Board of Girindus AG, said, "The awarding of these two contracts are significant steps in our commercial development strategy. They are clear demonstrations that our decision to build a strong team of leading professionals in quality systems and pharmaceutical manufacturing has convinced customers of our capability in the area of process validation, and about the excellent competencies of the new team we have assembled during the last 15 months."

In order to support the validation efforts of the team, Girindus is also pleased to announce that it has engaged Dr. Mark Guzman as its Validation Consultant. Dr. Guzman has worked previously with Pfizer and with Dynavax, where he played pivotal roles in the validation of manufacturing processes for complex oligonucleotide products.

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