April 9, 2021

Project Status - Lentiviral Vector Reference Material (LVV-RM)

Work Resumes Following COVID-19 Restrictions

As a result of our role in the 2001 Adenoviral, serotype 5 (Ad5) Reference Material Project, ISBioTech has been coordinating the LVV-RM project since its inception. I am writing to bring you up to date on the progress.

Testing: We are completing the cell line identity testing, plus *in vitro* safety testing for adventitious agents, mycoplasma, and sterility. All of this work has been donated. Then following the first pilot-scale run, we'll have the vector material tested for replication competence. And when production-scale material is available, we'll submit it for safety testing, as well as characterization by as many organizations as possible. FDA/CBER has agreed to analyze all the data and make it available for project documentation and publishing.

Consumables: We've obtained, or have been promised, all of the consumable materials needed for the pilot-scale runs, and almost everything we need for the production run.

Process Development: The National Research Council (NRC) of Canada is finalizing the process that will involve a stable cell line grown in suspension with serum-free medium, and purification with monolith chromatography. They are also working out the difficulties associated with sterile filtering this 120 nm virus. To view the entire process, please go to the latest PowerPoint presentation on our LVV-RM home page.

Sterile Filtration and Vialing: We must still find an organization that will thaw, sterile filter, and fill approximately 3,000 vials. So far, all of the organizations we've contacted have either been too busy or have otherwise been unwilling to take on this work, even though we have commitments to supply all the vials and closures. There simply aren't that many organizations that can do their own vialing, and even fewer that can vial viral vectors.

For more information, please contact me and visit our website.

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