Pfizer Statement on Results of Comparative Analysis of Tropism Assays

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(BUSINESS WIRE)--Pfizer Inc recently conducted a comparative analysis of the tropism assays TrofileTM, provided by Monogram Biosciences, and SensiTropTM, provided by Pathway Diagnostics. This analysis of 100 treatment experienced patient samples showed that the SensiTrop results were discordant with the results obtained using Trofile, which was used and clinically validated in the SelzentryTM (maraviroc) clinical trials.

Specifically, of the 39 samples previously identified as dual/mixed (D/M) or X4-tropic by Trofile, 19 were classified as R5-tropic by SensiTrop. These findings mean that there is a possibility that some patients whose tropism was assessed with SensiTrop may have received Selzentry based on an inaccurate R5 tropism reading.

Selzentry is only indicated for use in treatment-experienced patients infected with R5-tropic HIV-1. If Selzentry is selected as an active drug for patients infected with D/M or X4-tropic HIV, it may not contribute to virologic suppression and could result in emergence of resistance to other drugs in the treatment regimen.

Pfizer is communicating these results in the interest of ensuring the appropriate use of Selzentry. Full results of the analysis have been shared with the US Food and Drug Administration (FDA), Pathway Diagnostics and Monogram Biosciences. Pfizer will also submit the results for presentation at an upcoming HIV medical congress.

Trofile was the tropism assay used to screen adult HIV patients during the Selzentry clinical development program. The safety and efficacy of Selzentry has been shown in treatment experienced patients who were infected with R5-tropic HIV-1 as determined by the Trofile assay. Results from a study conducted in patients with D/M-tropic HIV-1 (using the Trofile assay) indicated that there was no significant reduction in viral load when

Selzentry was added to optimized background therapy. Therefore, the accurate determination of tropism is essential to the appropriate use of Selzentry.

Physicians who may have made treatment decisions based on the tropism results from the SensiTrop assay and who have questions about this analysis can obtain more information by calling Pfizer at 1 800 879 3477.

Selzentry, in combination with other antiretroviral agents, is indicated for treatment-experienced adult patients infected with only R5-tropic HIV-1 detectable, who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents. For full prescribing information for Selzentry, including boxed warning, go to www.Selzentry.com.

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