



PRESS RELEASE

Shionogi-GlaxoSmithKline Pharmaceuticals Acknowledges Position of the European AIDS Treatment Group and the AIDS Treatment Activists Coalition to Revise Protocol for ING112276, a Clinical Study for S/GSK1349572

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Shionogi-GlaxoSmithKline Pharmaceuticals, LLC, in collaboration with the European AIDS Treatment Group (EATG) and the Drug Development Committee (DDC) of the AIDS Treatment Activists Coalition (ATAC), today announces plans to revise inclusion criteria for Study ING112276. The ING112276 study is a dose-ranging study of the investigational integrase inhibitor S/GSK1349572 in antiretroviral therapy-naïve patients.

In response to evolving regulatory recommendations and HIV community consensus on the appropriate patients to include in dose-ranging studies of investigational agents, the amendment increases the minimum allowable CD4+ cell count to 200 cells/mm³ (or higher as local guidelines dictate). Patients with lower CD4+ counts should be treated with established standard of care agents, as their immediate need for therapy is greater.

“Working together, we are able to draw upon the collective expertise of the HIV community, patients, clinicians, researchers and regulatory agencies to develop new medicines for the treatment of people living with HIV and AIDS,” commented Dr. Garrett Nichols, Co-Project Leader for the clinical development of S/GSK1349572, Shionogi-GlaxoSmithKline Pharmaceuticals, LLC. “Though the original protocol inclusion criteria were aligned with current practices and precedents and agreed with the appropriate regulatory and ethical review boards, the additional perspectives offered by the HIV community are important in this rapidly evolving field. We are pleased to acknowledge the positions of the EATG and DDC on this issue.”

He continued, “It is important to stress that the rationale for this change is not based upon any new data or safety concern for S/GSK1349572 specifically, or integrase inhibitors in general. Rather, we are committed to focusing on the needs of the broader HIV community, thereby prioritizing patients in all of our work.”

Implemented in June 2009, the EMEA Guidelines on the Clinical Development of Medicinal Products for the Treatment of HIV Infection¹ for exploratory studies in HIV-infected individuals state that treatment-naïve patients in need of immediate therapy under current guidelines (i.e. those with CD4+ T-cell count below about 200 cells/mm³ or symptomatic patients) should be included in exploratory studies only if there is a scientific rationale and if data are available from patients with higher T-cell counts. Due to the importance of first-line therapy in these patients, appropriate antiretroviral activity should be documented. Therefore, the use of an experimental compound in suboptimal doses, dose intervals, or combinations, should be excluded with reasonable certainty prior to beginning studies in these patients.

“The EATG supports this position and believes there is a need for review and broader application of the European regulatory guidelines with respect to enrollment of treatment-naïve patients into clinical trials,” stated Wim Vandevelde, Chair, European Community Advisory Board. “We are pleased that GSK has listened to the concerns of the EATG and is taking a leadership position in the context of the varied interpretation of the existing guidelines. It is imperative that people with immediate need of initiating antiretroviral treatment are able to receive the optimal standard of care. The EATG calls for greater involvement of the HIV community in regulatory review panels at the regional and national level.”

¹ Ref. EMEA/CPMP/EWP/633/02

"Having pharmaceutical companies listen to and incorporate the concerns of AIDS activists is critical to designing safe and effective trials of HIV drugs," said David Evans, Co-chair of the DDC. "This is a good example of how that process can and should work. Activists have never sought to unnecessarily slow down drug development, only to promote the well-being of those who volunteer for the studies. That will be accomplished with this protocol amendment, and we are pleased that GSK is equally committed to prioritizing patients."

The undersigned groups call for further stakeholder discussion to review and agree definitive guidelines for recruitment of antiretroviral-naïve patients in dose-ranging trials of investigational agents, while simultaneously encouraging the pursuit of urgently needed new and innovative medicines for the treatment of HIV and AIDS.

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About Integrase Inhibitors

Integrase inhibitors are a new class of anti-HIV drugs that blocks HIV replication by preventing viral DNA from integrating into the genetic material of human immune cells (T-cells). This step is essential in the HIV-1 replication cycle. Integrase inhibitors are of great interest because they have a different mechanism of action than other anti-HIV drugs, and there is a need for new medications that help address resistance issues and provide additional treatment options. Patients need multiple, active antiretroviral drugs that can be administered in combination to attain viral suppression, as well as new drugs that offer different resistance profiles and simplified dosing.

About European AIDS Treatment Group

Established in 1992, the European AIDS Treatment Group (EATG) is a European network of nationally-based activists. As a European patient-led advocacy organization, it has been at the forefront of the development of the civil society response to the HIV/AIDS epidemic in Europe. It represents and defends the treatment-related interests of people living with HIV and AIDS. One of its working groups, the European Community Advisory Board (ECAB) aims to promote the harmonization of the best available clinical practices, standards of care and access to the latest and best available therapies and diagnostic tools throughout Europe, with a particular regard to Central and Eastern Europe.

About AIDS Treatment Activists Coalition

The AIDS Treatment Activists Coalition (ATAC) is a national coalition of AIDS activists, many living with HIV/AIDS, working together to end the AIDS epidemic by advancing research on HIV/AIDS. ATAC's Drug Development Committee (DDC) works with government, academia and the pharmaceutical industry to provide a community perspective into the development of new HIV drugs and the utilization of HIV therapies.

About Shionogi-GlaxoSmithKline Pharmaceuticals, LLC

Shionogi-GlaxoSmithKline Pharmaceuticals, LLC is a long-standing joint venture between Shionogi & Co., Ltd. and GlaxoSmithKline (GSK) which has made considerable progress in developing next-generation integrase inhibitors for the treatment of HIV. Launched in 2001, the joint venture was originally established for the development and commercialization of new agents to fight HIV and neurological disorders, including Alzheimer's, stroke, and head injury. More recently, the company has focused exclusively on several new integrase inhibitor candidates jointly discovered by Shionogi & Co., Ltd. and GSK.

European AIDS Treatment Group Contact:

Nikos Dedes +306 944 386 560 nikos.dedes@eatg.org

AIDS Treatment Activists Coalition Contact:

Jeff Berry +1 773 454 5333 jeffberry@ameritech.net

GlaxoSmithKline Contacts:

Scott Purdon – Director, Patient Relations
+44 208 047 4716 scott.d.purdon@gsk.com

Marc Meachem – Director, Product Communications
+1 919 483 8756 marc.s.meachem@gsk.com

Robin Fastenau – Director, Global Pipeline Communications
+1 919 483 7966 robin.e.fastenau@gsk.com