Final Business Plan

S10: Photosafety Evaluation of Pharmaceuticals

dated 8 April 2010

Endorsed by the ICH Steering Committee on 9 June 2010

1. The issue and its costs

There are some issues to be tackled to harmonise the guidelines. Firstly, criteria to initiate phototoxicity testing and triggers for additional testing should be defined. Secondly, the value of several test methods should be clarified. A data survey may be needed to set the criteria and appropriate test methods if published data have not adequately addressed these issues. The survey, however, requires companies to dedicate their staff to mine their existing data and the regulatory agencies to blind collected data for analysis by the EWG. Estimated costs may run up to several hundreds of thousand dollars for these efforts. Therefore, necessity for the survey should be carefully examined by the EWG and approved by the Steering Committee.

2. Planning

The main deliverable is a harmonised guideline for photosafety evaluation. If the data survey is absolutely required to achieve harmonisation, a paper may be published with permission from the companies submitting the data.

The ICH six parties are asked to nominate two members (toxicologists), and one member nominated by Health Canada, WHO and EFTA as observers.

A *Step 1* document will be drawn up during the first EWG meeting which is anticipated at the Fukuoka meeting in November 2010. If the EWG determines that a data survey is warranted to set the criteria to initiate the phototoxicity testing and to examine the correlation between nonclinical and clinical data, a questionnaire will be also generated at the meeting. The EWG will prepare *Step 2* document based on the gathered data in the survey. The *Step 2* document will be published for consultation in June 2012. After collecting and incorporating public comments, a *Step 4* document will be finalised in June 2013. If the EWG decides not to conduct the data survey, the topic will reach *Step 4* six months earlier.

3. The impacts of the project

Unnecessary *in vitro* and *in vivo* testing will be avoided if definitive, directive criteria for the need to conduct photosafety studies are published, which would save financial and animal recourses during the course of pharmaceutical development. More importantly, phototoxic agents could be identified more accurately with appropriate test methods contributing to improved human safety.

The EMA and FDA published “Note for guidance on photosafety testing” in 2002, and the FDA “Guidance for industry; Photosafety testing” in 2003, respectively. Later in 2008, the EMA stated the need for revision of the note for guidance on photosafety testing in their concept paper. The MHLW published a guidance on skin

photosensitization testing in 1989 and has set up a working team to establish comprehensive new guidance on photosafety testing. This forum would establish a more inclusive venue for the regulatory agencies and the industry to develop a common understanding and approach to the issue of photosafety testing.

4. Post-hoc evaluation

The EWG may re-evaluate the harmonised guideline when more data are accumulated after this topic reaches *Step 5* in each region.