Proposal No. : C2008-T12	**Acronym : U-BIOPRED**

IMI Consensus evaluation form - Stage 2

1. Scientific and/or technological excellence • Soundness and quality of approach to meet the objectives of the call topic • Application of creative and cutting edge methodologies (or for the Education & Training topics, establishment of creative and up- to-date training programs) • Uniqueness of the approach (no duplication of existing initiative) • Where applicable, any ethical issues appropriately addressed --- *[Evaluators' Comments]* *This is an excellent project which delivers in almost every aspect, in keeping with the Call.* *However the Panel has a few reservations which require to be addressed :* 1. *Rhino viral Infection models - The investigators should provide a detailed timeline for the development of the GMP quality viral particles and a plan for validation of the protocol in other sites within the Consortium. Please identify the expert/s for construction of the above viral particles.* 2. *Subject recruitment and selection – The investigators must clarify the criteria by which the members will uniformly recruit and select their patients, specifically in relation to the exacerbation studies.* 3. *The consortium should provide an annual report for external review.*	☐ Acceptable (excellent) x Acceptable (subject to specified adjustment) ☐ Not acceptable

2. Excellence of the project implementation plan • Adequate and appropriate representation of all relevant stakeholders within the consortium. • Adequate documentation of the project plan with efficient timelines and well utilised resources. Includes justification of timelines and resource allocation (e.g. for research, management, training or other activities). • Resource allocation (by value) by the EFPIA project participants should at least equal the funding requested by the participants eligible for funding by the IMI JU *(if not,* the unequal resource allocation is adequately justified). • Adequate documentation and appropriateness of the management structure and procedures. Management plan capable of building a cohesive and efficient team within the consortium --- *[Evaluators' comments.]* *The consortium delivers on a broad public-academic-pharma interaction and expertise. There is a sound management plan. The Panel now requests clarification regarding :* 1. *Humanised Mouse Model – please revise the timeline for this task as the time allocation given for this appears too short to produce meaningful results.* 2. *Budget resources – (i) please clarify the direct budget allocations to Institutions involved with paediatric studies; (ii) consider re-allocating resources depending on (a) results and (b) individual site output / productivity.* 3. *Conflict of interest – require clarification with (i) representation of stakeholders within the consortium for example the lead scientist for participant 5 'wears another hat' as participant 26. Participant 3 and 29 have very close business ties and it is difficult to tease out from the proposal whether there is duplication of tasks. The dual function of participants should be taken into account during resource allocation; (ii) clarify how the various patient/care organisations are going to work together and what are their individual tasks in dissemination. The panel recommends that the consortium uses existing resources e.g. ERS / ELF websites for communication and dissemination, and ELF for co-ordination of links with patient/carer organisations.*	☐ Acceptable (excellent) x Acceptable (subject to specified adjustment) ☐ Not acceptable

3. Consistency with Call Topic and stage 1 • Scope of Full Project Proposal is consistent with the Call Topic published in May 2008. • Full Project Proposal contains core objectives and plans that do not substantially deviate in scope from the Expression of Interest selected at Stage 1, except to fulfil recommendations from the Stage 1 peer review. • The composition of the applicant consortium does not substantially deviate from that described in the Expression of Interest selected at Stage 1, except where adequately justified or to fulfil recommendations from the Stage 1 peer review. --- *[Evaluators' comments]* *The scope of the full project proposal is consistent and highly relevant with the call topic and does not deviate in scope from information provided at Stage 1.*	☒ Acceptable ☐ Not acceptable
4. Potential impact of project results Likelihood of IMI key benefits (i.e. new multidisciplinary development tools, new development paradigms) to be achieved following dissemination / publication of research results. For the Education & Training topics, likelihood of pan-European access to high-quality training for biomedical R&D, and likelihood of graduates, career scientists, and scientific stakeholders being better educated and trained in innovative pharmaceutical science. --- *[Evaluators' comments.]* *The Panel is mindful of a successful outcome of the programme, likely to produce results which may have a significant impact on identification of risk factors associated with severe asthma development.* *In view of the medical/societal impact of asthma, the proposed research will lead to interactive and bidirectional training of scientists in academia and Industry complemented by close collaboration with patient organisations. This is likely to have a positive impact on public perception of scientific research.*	☒ High impact ☐ Medium impact ☐ Low impact
A Draft Project Agreement is attached	**Yes** ☒ **No** ☐

Overall Evaluation The Full Project Proposal will be considered as "overall not acceptable" if any of the first three criteria has been scored as "not acceptable". --- *[Evaluators' recommendations.]* As above	☐ **Overall Acceptable** (excellent) x **Overall Acceptable** (subject to specified adjustments) ☐ **Overall Not Acceptable**