Global Drug Development

Effective July 1, 2016, we established a Global Drug Development (GDD) organization to oversee drug development activities for our Innovative Medicines Division and the biosimilars portfolio of our Sandoz Division. GDD works collaboratively with the Novartis Institutes for Biomedical Research (NIBR), our Innovative Medicines Division and our Sandoz Division to execute our overall pipeline strategy and takes an enterprise approach to pipeline portfolio management. Key elements of the new GDD organization incorporate centralized global functions such as Regulatory Affairs and Global Development Operations, and Global Development units/franchises aligned with our business franchises. GDD was created to improve resource allocation, technology implementation and process standardization to further increase innovation. GDD includes approximately 10,000 associates worldwide.

Under our Global Drug Development unit, the focus of our development program is to determine the safety and efficacy of a potential new medicine in humans.

Drug development

The traditional model of development comprises three phases, which are defined as follows:

Phase I: These are the first clinical trials of a new compound, generally performed in a small number of healthy human volunteers, to assess the drug’s safety profile, including the safe dosage range. These trials also determine how a drug is absorbed, distributed, metabolized and excreted, and the duration of its action.

Phase II: Clinical studies performed with patients who have the target disease, with the aim of continuing the Phase I safety assessment in a larger group, assessing the efficacy of the drug in the patient population, and determining the appropriate doses for further evaluation.

Phase III: Large-scale clinical studies with several hundred to several thousand patients, which are conducted to establish the safety and efficacy of the drug in specific indications for regulatory approval. Phase III trials may also be used to compare a new drug against a current standard of care to evaluate the overall benefit-risk relationship of the new medicine.

In each of these phases, physicians monitor volunteer patients closely to assess the potential new drug’s safety and efficacy.

Though we use this traditional model as a platform, we have tailored the development process to be simpler, more flexible and efficient. We view the development process as generally consisting of Exploratory Development where “proof of concept” is established, and Confirmatory Development where this concept is confirmed in large numbers of patients. Exploratory Development consists of clinical “proof of concept” (PoC) studies, which are small clinical trials (typically 5-15 patients) that combine elements of traditional Phase I/II testing. These customized trials are designed to give early insights into issues such as safety, efficacy and toxicity for a drug in a given indication and are conducted by NIBR. Once a positive proof of concept has been established, the drug moves to the Confirmatory Development stage and becomes the responsibility of GDD. Confirmatory Development has elements of traditional Phase II/III testing and includes trials aimed at confirming the safety and efficacy of the drug in the given indication leading up to submission of a dossier to health authorities for approval. Like traditional Phase III testing, this stage can also include trials which compare the drug to the current standard of care for the disease, in order to evaluate the drug’s overall risk/benefit profile.
The vast amount of data that must be collected and evaluated makes clinical testing the most time-consuming and expensive part of new drug development. The next stage in the drug development process is to seek registration for the new drug.

Registration/post-launch

To register a new drug, the results of all preclinical and clinical studies, along with the description of the manufacturing process, are compiled and submitted to regulatory authorities. If regulators agree that the data establish the quality, efficacy and safety of the drug, a marketing authorization is granted. The new drug can then be made commercially available to patients. Once a drug is on the market, adverse effects need to be constantly monitored and reported to regulatory authorities. In addition, life-cycle programs – including Phase IV clinical trials – are often undertaken to explore and add new indications or improve existing formulations of the drug.

At each phase of clinical development, our activities are managed by our Innovation Management Board (IMB). The IMB is responsible for oversight over all major aspects of our development portfolio and oversees our drug development budget. In particular, the IMB is responsible for the endorsement of proposals to commence the first clinical trials of a development compound, and of major project phase transitions and milestones following a positive proof of concept outcome, including transitions to full development and the decision to submit a regulatory application to the health authorities. The IMB is also responsible for project discontinuations, for the endorsement of overall development strategy and the endorsement of development project priorities. The IMB is chaired by our Global Head of Drug Development and Chief Medical Officer and has representatives from Novartis senior management, as well as experts from a variety of fields among its core members and extended membership.

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Such forward looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should any one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward looking statements. There can be no guarantee that any new products will be approved for sale in any market, or that any new indications will be approved for any existing products in any market, or that any approvals which are obtained will be obtained at any particular time, or that any such products will achieve any particular revenue level. Nor can there be any guarantee that the review of options being undertaken to maximize shareholder value of the Alcon Division will reach any particular results, or at any particular time. Neither can there be any guarantee that Novartis will be able to realize any of the potential strategic benefits, synergies or opportunities as a result of the significant reorganizations of recent years, including the creation of the Pharmaceuticals and Oncology business units to form the Innovative Medicines Division, the creation of the Global Drug Development organization and Novartis Operations (including Novartis Technical Operations and Novartis Business Services), the transfer of the Ophthalmic Pharmaceuticals products of our Alcon Division to the Innovative Medicines Division, the transfer of selected mature, non-promoted pharmaceutical products from the Innovative Medicines Division to the Sandoz Division, and the transactions with GSK, Lilly and CSL. Neither can there be any guarantee that shareholders will achieve any particular level of shareholder returns. Nor can there be any guarantee that the Group, or any of its divisions, will be commercially successful in the future, or achieve any particular credit rating or financial results. In particular, our expectations could be affected by, among other things: regulatory actions or delays or government regulation generally; the potential that the strategic benefits, synergies or opportunities expected from the significant reorganizations of recent years, including the creation of the Pharmaceuticals and Oncology business units to form the Innovative Medicines Division, the creation of the Global Drug Development organization and Novartis Operations (including Novartis Technical Operations and Novartis Business Services), the transfer of the Ophthalmic Pharmaceuticals products of our Alcon Division to the Innovative Medicines Division, the transfer of selected mature, non-promoted pharmaceutical products from the Innovative Medicines Division to the Sandoz Division, and the transactions with GSK, Lilly and CSL may not be realized or may take longer to realize than expected; the inherent uncertainties involved in predicting shareholder returns or credit ratings; the uncertainties inherent in the research and development of new healthcare products, including clinical trial results and additional analysis of existing clinical data; our ability to obtain or maintain proprietary intellectual property protection, including the ultimate extent of the impact on Novartis of the loss of patent protection and exclusivity on key products which commenced in prior years and will continue this year; safety, quality or manufacturing issues; global trends toward health care cost containment, including government, payer and general public pricing and reimbursement pressures; the particular prescribing preferences of physicians and patients; uncertainties regarding actual or potential legal proceedings, including, among others, actual or potential product liability litigation, litigation and investigations regarding sales and marketing practices, intellectual property disputes and government investigations generally; general economic and industry conditions, including uncertainties regarding the effects of the persistently weak economic and financial environment in many countries; uncertainties regarding future global exchange rates; uncertainties regarding future demand for our products; and uncertainties regarding potential significant breaches of data security or data privacy, or disruptions of our information technology systems; and other risks and factors referred to in Novartis AG’s current Form 20-F.