Global Drug Development

Our Global Drug Development (GDD) organization oversees all drug development activities for our Innovative Medicines Division and collaborates with our Sandoz Division on development of its biosimilars portfolio. GDD works collaboratively with the Novartis Institutes for Biomedical Research (NIBR), Innovative Medicines and Sandoz to execute our overall pipeline strategy. The GDD organization includes centralized global functions such as Regulatory Affairs and Global Development Operations, as well as Global Development units aligned with our business franchises. GDD includes approximately 11,000 full-time equivalent associates worldwide.

Accordion:
Drug development

The traditional model of development consists of three phases:

Phase I: 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, we have tailored the development process to be simpler, more flexible and efficient. We divide the development process into two stages: Exploratory Development to establish proof of concept, followed by Confirmatory Development to confirm the concept in large numbers of patients. Exploratory Development consists of clinical proof-of-concept (PoC) studies, which are small clinical trials (typically involving in the range of between five and 15 patients) that combine elements of traditional Phase I/II testing. NIBR conducts these customized trials, which are designed to give early insights into issues such as safety, efficacy and toxicity for a drug in a given indication. 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. This stage can also include trials that compare the drug to the current standard of care for the disease in order to evaluate the drug’s overall risk-benefit profile. Further, with new treatment approaches such as gene therapy for rare diseases, elements of Exploratory and Confirmatory Development may be combined and suffice for registration under certain conditions such as high unmet medical need and clinical data showing highly favorable benefit-risk. In these cases, additional post-approval studies may be required by the regulatory authorities to continue to gather important data to further support approval.

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.

Our Innovation Management Board (IMB) manages our activities at each phase of clinical development. The IMB is responsible for all major aspects of our development portfolio and oversees our drug development budget as well as major project phase transitions and milestones following a positive proof-of-concept outcome, including transitions to Confirmatory Development and the decision to submit a regulatory application to the health authorities. The IMB is also responsible for the endorsement of the overall development strategy, the endorsement of development project priorities, and decisions on project discontinuations. Our Chief Executive Officer chairs the IMB and other representatives from Novartis senior management, with expertise spanning multiple fields, are among its core members and extended membership.

Disclaimer:

These materials contain forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995, that can generally be identified by words such as “potential,” “expected,” “will,” “planned,” “pipeline,” “outlook,” “may,” “could,” “would,” “anticipate,” “seek,” or similar expressions, or by express or implied discussions regarding potential new products, potential new indications for existing products, potential product launches, or regarding potential future revenues from any such products; or regarding the development or adoption of potentially transformational technologies, treatment modalities and business models; or regarding potential future or pending transactions, including the potential outcome, or financial or other impact on Novartis, of the proposed divestiture of certain portions of our Sandoz Division business in the US; or regarding the potential impact of share buybacks; or regarding potential future sales or earnings of the Group or any of its divisions or potential shareholder returns; or by discussions of strategy, plans, expectations or intentions. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should 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. You should not place undue reliance on these statements. In particular, our expectations could be affected by, among other things: global
trends toward healthcare cost containment, including ongoing government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; uncertainties regarding potential significant breaches of data security or data privacy, or disruptions of our information technology systems; regulatory actions or delays or government regulation generally, including potential regulatory actions or delays with respect to the proposed transactions or the development of the products described in these materials; the potential that the proposed divestiture of certain portions of our Sandoz Division business in the US or the planned acquisition of the Japanese operations and associated assets of Aspen Global Incorporated may not be completed in the expected time frame, or at all; the potential that the strategic benefits, synergies or opportunities expected from the acquisition of The Medicines Company, the proposed divestiture of certain portions of our Sandoz Division business in the US, or the planned acquisition of the Japanese operations and associated assets of Aspen Global Incorporated, and other transactions described, may not be realized or may be more difficult or take longer to realize than expected; the successful integration of The Medicines Company into the Novartis Group and the timing of such integration; potential adverse reactions to the transaction by customers, suppliers or strategic partners; dependence on key personnel of The Medicines Company; dependence on third parties to fulfill manufacturing and supply obligations; the uncertainties involved in predicting shareholder returns; the uncertainties 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 that commenced in prior years and is expected to continue this year; safety, quality, data integrity, or manufacturing issues; uncertainties involved in the development or adoption of potentially transformational technologies and business models; uncertainties regarding actual or potential legal proceedings, including, among others, product liability litigation, disputes and litigation with business partners or business collaborators, government investigations generally, litigation and investigations regarding sales and marketing practices, and intellectual property disputes; our performance on environmental, social and governance measures; general political, economic and trade conditions, including uncertainties regarding the effects of ongoing instability in various parts of the world; uncertainties regarding future global exchange rates; uncertainties regarding future demand for our products; and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in these materials as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

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