



Development of Biosimilars in the U.S. – Teva's Position on Key Issues

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Forward-looking statements



TEVA

TODAY'S PRESENTATION CONTAINS FORWARD-LOOKING STATEMENTS, WHICH EXPRESS THE CURRENT BELIEFS AND EXPECTATIONS OF MANAGEMENT. SUCH STATEMENTS INVOLVE A NUMBER OF KNOWN AND UNKNOWN RISKS AND UNCERTAINTIES THAT COULD CAUSE OUR FUTURE RESULTS, PERFORMANCE OR ACHIEVEMENTS TO DIFFER SIGNIFICANTLY FROM THE RESULTS, PERFORMANCE OR ACHIEVEMENTS EXPRESSED OR IMPLIED BY SUCH FORWARD-LOOKING STATEMENTS. IMPORTANT FACTORS THAT COULD CAUSE OR CONTRIBUTE TO SUCH DIFFERENCES INCLUDE RISKS RELATING TO: OUR ABILITY TO SUCCESSFULLY DEVELOP AND COMMERCIALIZE ADDITIONAL PHARMACEUTICAL PRODUCTS, THE INTRODUCTION OF COMPETING GENERIC EQUIVALENTS, THE EXTENT TO WHICH WE MAY OBTAIN U.S. MARKET EXCLUSIVITY FOR CERTAIN OF OUR NEW GENERIC PRODUCTS AND REGULATORY CHANGES THAT MAY PREVENT US FROM UTILIZING EXCLUSIVITY PERIODS, POTENTIAL LIABILITY FOR SALES OF GENERIC PRODUCTS PRIOR TO A FINAL RESOLUTION OF OUTSTANDING PATENT LITIGATION, INCLUDING THAT RELATING TO THE GENERIC VERSIONS OF NEURONTIN®, LOTREL®, PROTONIX® AND YAZ®, CURRENT ECONOMIC CONDITIONS, THE EXTENT TO WHICH ANY MANUFACTURING OR QUALITY CONTROL PROBLEMS DAMAGE OUR REPUTATION FOR HIGH QUALITY PRODUCTION, THE EFFECTS OF COMPETITION ON OUR INNOVATIVE PRODUCTS, ESPECIALLY COPAXONE® SALES, DEPENDENCE ON THE EFFECTIVENESS OF OUR PATENTS AND OTHER PROTECTIONS FOR INNOVATIVE PRODUCTS, ESPECIALLY COPAXONE®, THE IMPACT OF CONSOLIDATION OF OUR DISTRIBUTORS AND CUSTOMERS, THE IMPACT OF PHARMACEUTICAL INDUSTRY REGULATION AND PENDING LEGISLATION THAT COULD AFFECT THE PHARMACEUTICAL INDUSTRY, OUR ABILITY TO ACHIEVE EXPECTED RESULTS THROUGH OUR INNOVATIVE R&D EFFORTS, THE DIFFICULTY OF PREDICTING U.S. FOOD AND DRUG ADMINISTRATION, EUROPEAN MEDICINES AGENCY AND OTHER REGULATORY AUTHORITY APPROVALS, THE UNCERTAINTY SURROUNDING THE LEGISLATIVE AND REGULATORY PATHWAY FOR THE REGISTRATION AND APPROVAL OF BIOTECHNOLOGY-BASED PRODUCTS, THE REGULATORY ENVIRONMENT AND CHANGES IN THE HEALTH POLICIES AND STRUCTURES OF VARIOUS COUNTRIES, ANY FAILURES TO COMPLY WITH THE COMPLEX MEDICARE AND MEDICAID REPORTING AND PAYMENT OBLIGATIONS, THE EFFECTS OF REFORMS IN HEALTHCARE REGULATION, SUPPLY INTERRUPTIONS OR DELAYS THAT COULD RESULT FROM THE COMPLEX MANUFACTURING OF OUR PRODUCTS AND OUR GLOBAL SUPPLY CHAIN, INTERRUPTIONS IN OUR SUPPLY CHAIN OR PROBLEMS WITH OUR INFORMATION TECHNOLOGY SYSTEMS THAT ADVERSELY AFFECT OUR COMPLEX MANUFACTURING PROCESSES, POTENTIAL TAX LIABILITIES THAT MAY ARISE SHOULD OUR AGREEMENTS (INCLUDING INTERCOMPANY ARRANGEMENTS), BE CHALLENGED SUCCESSFULLY BY TAX AUTHORITIES, OUR ABILITY TO SUCCESSFULLY IDENTIFY, CONSUMMATE AND INTEGRATE ACQUISITIONS AND OTHER BUSINESS COMBINATIONS (INCLUDING OUR PENDING ACQUISITION OF RATIOPHARM), THE POTENTIAL EXPOSURE TO PRODUCT LIABILITY CLAIMS TO THE EXTENT NOT COVERED BY INSURANCE, OUR EXPOSURE TO FLUCTUATIONS IN CURRENCY, EXCHANGE AND INTEREST RATES, AS WELL AS TO CREDIT RISK, SIGNIFICANT OPERATIONS WORLDWIDE THAT MAY BE ADVERSELY AFFECTED BY TERRORISM, POLITICAL OR ECONOMICAL INSTABILITY OR MAJOR HOSTILITIES, OUR ABILITY TO ENTER INTO PATENT LITIGATION SETTLEMENTS AND THE INCREASED GOVERNMENT SCRUTINY OF OUR AGREEMENTS WITH BRAND COMPANIES IN BOTH THE U.S. AND EUROPE, THE TERMINATION OR EXPIRATION OF GOVERNMENTAL PROGRAMS AND TAX BENEFITS, IMPAIRMENT OF INTANGIBLE ASSETS AND GOODWILL, ANY FAILURE TO RETAIN KEY PERSONNEL OR TO ATTRACT ADDITIONAL EXECUTIVE AND MANAGERIAL TALENT, ENVIRONMENTAL RISKS, AND OTHER FACTORS THAT ARE DISCUSSED IN OUR ANNUAL REPORT ON FORM 20-F FOR THE YEAR ENDED DECEMBER 31, 2009, IN THIS REPORT AND IN OUR OTHER FILINGS WITH THE U.S. SECURITIES AND EXCHANGE COMMISSION ("SEC").



- Teva is the world's largest generic company and the 11th largest global pharmaceutical company
- Over the last 10 years, Teva invested heavily in biosimilars:
 - establishing R&D and manufacturing infrastructure
 - acquiring technologies
 - developing partnerships in this field
 - experience of bringing a biosimilar product to the European marketplace
- Teva is developing a broad and deep pipeline of biosimilars that target serious medical conditions with the aim of providing better health to more patients at more affordable prices



- We consider the establishment of a biosimilar pathway in the U.S. an important initiative that could:
 - improve access to these highly expensive drugs
 - reduce the economic burden biotech drugs currently pose on the US healthcare system (expected to exceed \$50B this year)



- When determining the requirements for the establishment of biosimilarity, Teva believes that a balanced approach is needed:
 - On the one hand, the complex nature of biologics warrants a cautious approach, and solid clinical evidence of similarity is needed before FDA recognizes a product as biosimilar
 - On the other hand, conducting unnecessary clinical trials raises ethical concerns and needlessly increases development costs, which may render biosimilars less affordable to patients



- Quality standards for biosimilars should be set at the highest level
- Reference product should be thoroughly characterized and the biosimilar should be developed to be within the variability range of the reference product



- Any biosimilar development program should include a robust pivotal clinical trial in one indication which will demonstrate similarity to the innovator's reference product in terms of safety and efficacy
- Once biosimilarity has been established in one indication, the applicant could seek other indications of the innovator product that share the same mechanism of action
- Robust pivotal clinical trial and safety measures must be undertaken to ensure public confidence and patient uptake of biosimilar product



- The biosimilar products should have the same INN name as the innovator, and be differentiated only by its trade name
- In order to avoid unnecessary replication of clinical trials, documented evidence or data generated in studies using innovator's reference product in one region should be acceptable in other regions



- Post marketing studies may be justified when there is a scientific rationale and a clear safety or efficacy need
- Interchangeability should be allowed, once biosimilarity has been established following a development program which included a robust pivotal clinical trial