Diabetes drug development is riskier compared to all drug development

One in 13 investigational diabetes drugs receives U.S. marketing approval

- 44% of new endocrine drugs approved in the United States in 1995-15 were for diabetes and related conditions.
- Large molecule products accounted for 33% of diabetes, and 20% of non-endocrine, drug approvals.
- After declining from the 1995-02 to the 2002-08 periods, mean clinical development time for diabetes drugs increased.
- During 1995-15, mean regulatory approval phase time was 15.7 months for diabetes drugs.
- Median clinical development time for diabetes drugs declined about 7% from 1995-01 to 2002-08 before increasing notably.

Investment in drug development focusing on diabetes and diabetes-related conditions continues to grow, as demand for new therapies tracks continued growth in diagnoses of the disease. Since the mid-1990s, scores of new diabetes and non-diabetes endocrine drugs have been launched. The 61 diabetes and non-diabetes endocrine products that received Food and Drug Administration (FDA) approval in the 1995-15 period accounted for 10% of all FDA new therapeutic drug approvals during that time.

Perhaps most noteworthy is that diabetes drug development, compared to drug development generally, is particularly risky, with only one in 13 investigational diabetes drugs receiving marketing approval, compared to one in eight of all drugs. However, although diabetes drugs that enter the clinical pipeline are less likely to enter Phase III testing, compared to all drugs, once in Phase III, diabetes drugs enjoy slightly higher approval rates. This report provides a summary of the development pathways and characteristics for 27 diabetes, 34 non-diabetes endocrine, and 573 non-endocrine new therapeutic drugs approved over 21 years ending in 2015.