Type 2 Diabetes (Fixed-Dose Combinations)

Type 2 diabetes is a major public health concern, affecting more than 30 million people in the United States alone. A newly diagnosed type 2 diabetic is usually prescribed metformin and lifestyle modification, but as the disease progresses, these patients will be prescribed either additional oral antidiabetic agents or insulin therapy. Because type 2 diabetes patients often take multiple pills for their condition as well as other comorbidities, physicians see fixed-dose combinations (FDCs) as a way to improve convenience and patients’ compliance if they already have a high pill burden. In this report we compare current FDCs used to treat type 2 diabetes and explore which FDCs in development will help to meet the unmet needs identified by physicians and payers.

Questions Answered in This Report:

- A drug’s performance on at least seven efficacy end points, including reduction in HbA1c level, is important for drug approval and physician use. What are the key primary and secondary clinical trial end points with which new therapies are evaluated? How do U.S. and European endocrinologists weight efficacy measures and other drug attributes in their prescribing decisions for type 2 diabetes?

- Greater reduction in body weight and HbA1c levels are key areas of unmet need for type 2 diabetes, according to the insights of surveyed U.S. and European endocrinologists. Which therapies in development for type 2 diabetes are poised to fulfill these needs? What clinical and/or regulatory challenges must drug developers overcome in order to capitalize on these areas of unmet need? What degree of improvement over currently available therapies do surveyed U.S. MCO PDs seek from new therapies on key clinical attributes for which surveyed physicians indicate high unmet need?

- By 2017 insulin degludec/liraglutide will emerge as the gold-standard therapy in our Drug Comparator Model because of its superior clinical profile over the key current therapies we evaluated. On what clinical attributes is insulin degludec/liraglutide most differentiated from its competitors? Which current therapies are at greatest risk of being replaced by insulin degludec/liraglutide?

Scope:

Attributes included in conjoint analysis-based assessment of target product profiles for type 2 diabetes:
- Reduction in HbA₁c levels.
- Effect on body weight.
- Incidence of hypoglycemia.
- Incidence of major cardiovascular adverse events.
- Route of administration.
- Dosing frequency.
- Price/day.

Attributes included in assessment of U.S. payers’ receptivity to new therapies for type 2 diabetes:
- Effect on HbA₁c levels.
- Effect on body weight.
- Incidence of hypoglycemia.
- Dosing frequency.

Physicians surveyed: 60 U.S. and 32 European endocrinologists.

Payers surveyed: 20 U.S. MCO PDs.

Comprehensive List of Therapies Included in Our Research and Modeling:

**Current Therapies**
- Sitagliptin/metformin (Merck’s Janumet)
- Saxagliptin/metformin XR (AstraZeneca’s Kombiglyze XR)
- Pioglitazone/metformin (Takeda’s Actoplus Met/Competact/Metact, generics)
- Glyburide/metformin (Bristol-Myers Squibb’s Glucovance, Sanofi’s Suguan M, Solvay’s GlicoRest, Abiogen’s Glicnorm, Roche’s BiEuglucon, generics)
- Pioglitazone/glimepiride (Takeda’s Duetact/Tandemact/Sonias)

**Emerging Therapies**
- Dapagliflozin/metformin (AstraZeneca’s Xigduo)
- Linagliptin/empagliflozin (Boehringer Ingelheim/Eli Lilly)
- Alogliptin/pioglitazone (Takeda/Furiex’s Oseni/Incresync/Liovel)
- Insulin degludec/liraglutide (Novo Nordisk’s Xultophy)
- Insulin glargine/lixisenatide (Sanofi/Zealand Pharma’s LixiLan)

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