



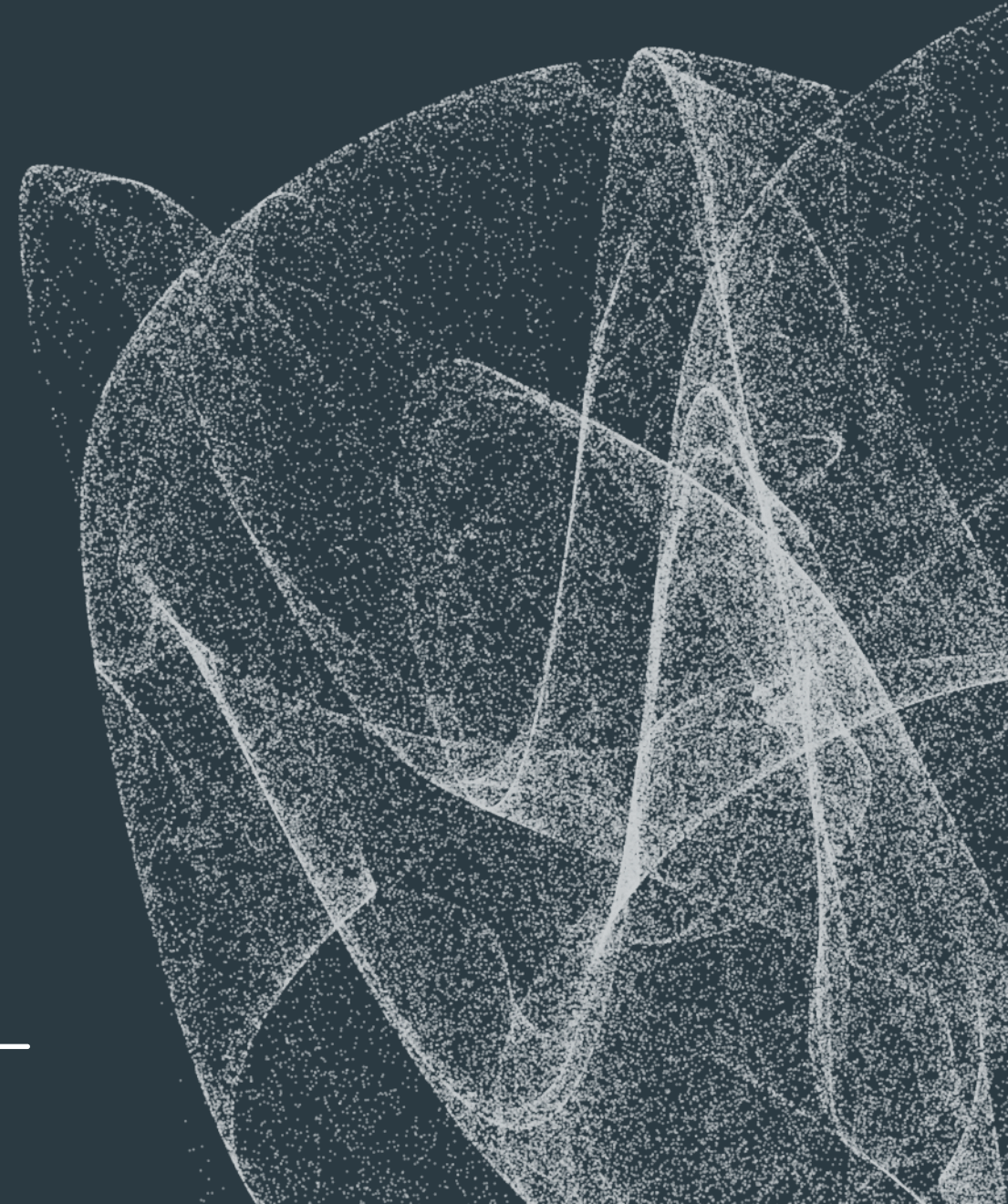
Biologics Market Dynamics: Setting the Stage for Biosimilars

FDA/FTC Workshop on a Competitive
Marketplace for Biosimilars

MARCH 9, 2020

Murray Aitken, Executive Director

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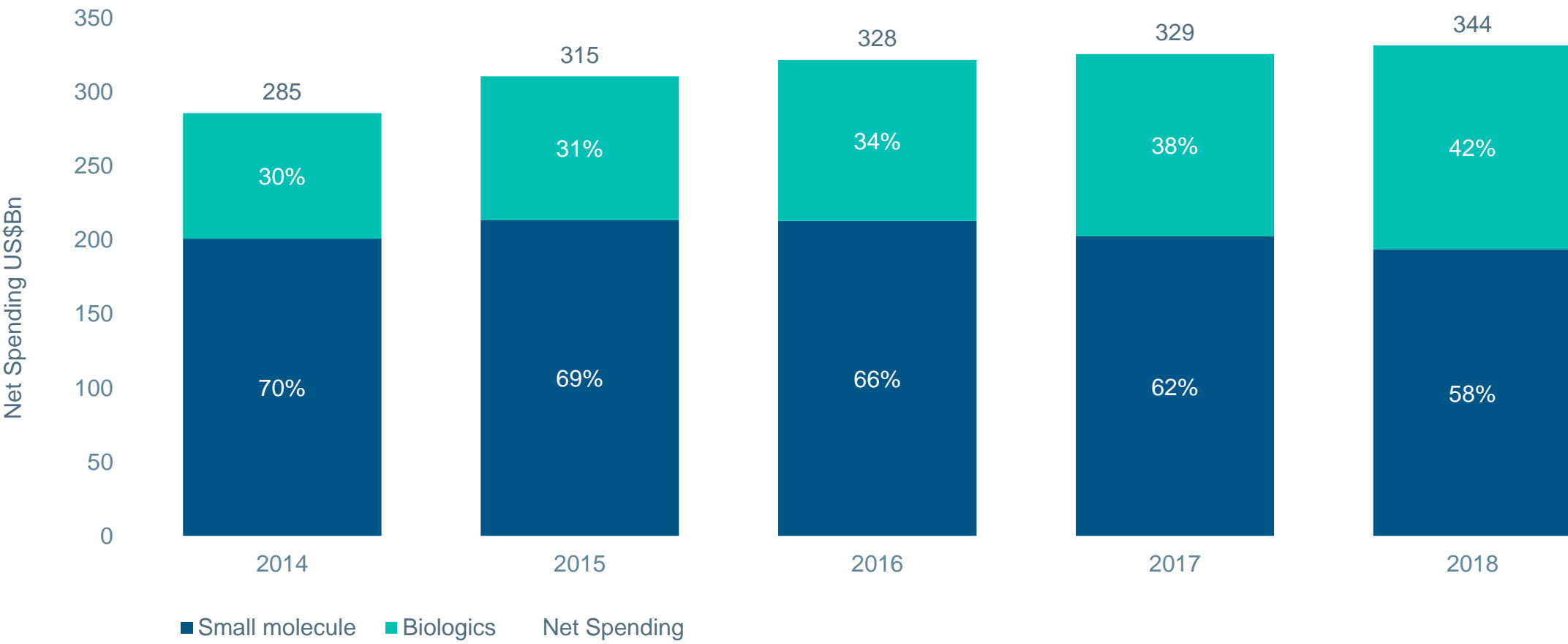


Biologics Market Dynamics

- Biologics are a growing share of the pharmaceutical market with significant growth over the past five years relative to small molecules
- The R&D pipeline suggests this growth dynamic will continue and be broad-based across most disease areas
- Biologics reach the market through multiple channels and paytypes, each with its own characteristics and payment dynamics
- The largest biologic originator brands have achieved significant cumulative sales since their launch
- Market exclusivity dynamics for small molecules are generally consistent and a steady share of the market is subject to competition from generics, which dominate volume share
- Market exclusivity dynamics for large molecules have begun to shift over the past three years in terms of exposure to biosimilar competition and shares

Biologics now represent 42% of the total medicines market, up from 30% in 2014

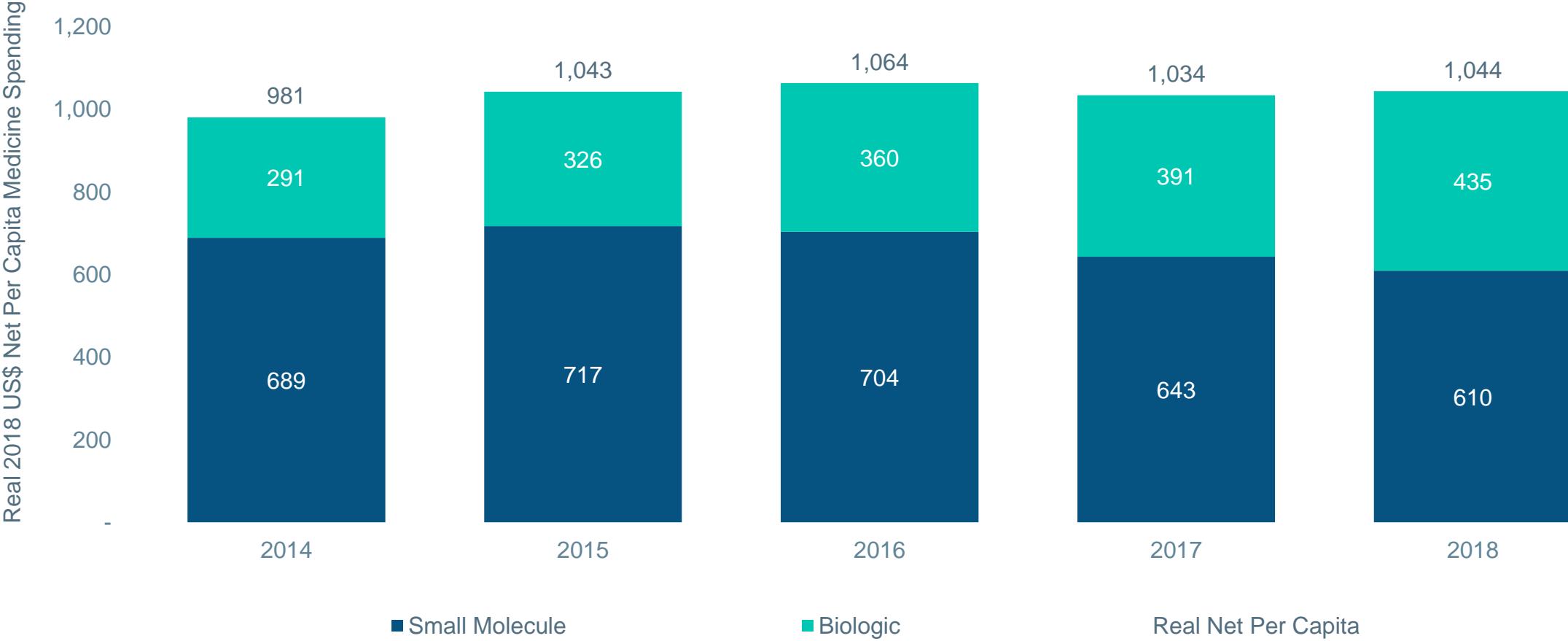
Net Medicine Spending by Product Type US\$Bn



Source: IQVIA, National Sales Perspectives, IQVIA Institute, Jan 2019; U.S. Census Bureau; U.S. Bureau of Economic Analysis (BEA), Dec 2018

Small molecules have declined 12% since 2014 on a real net per capita basis, while biologics have increased by 50%

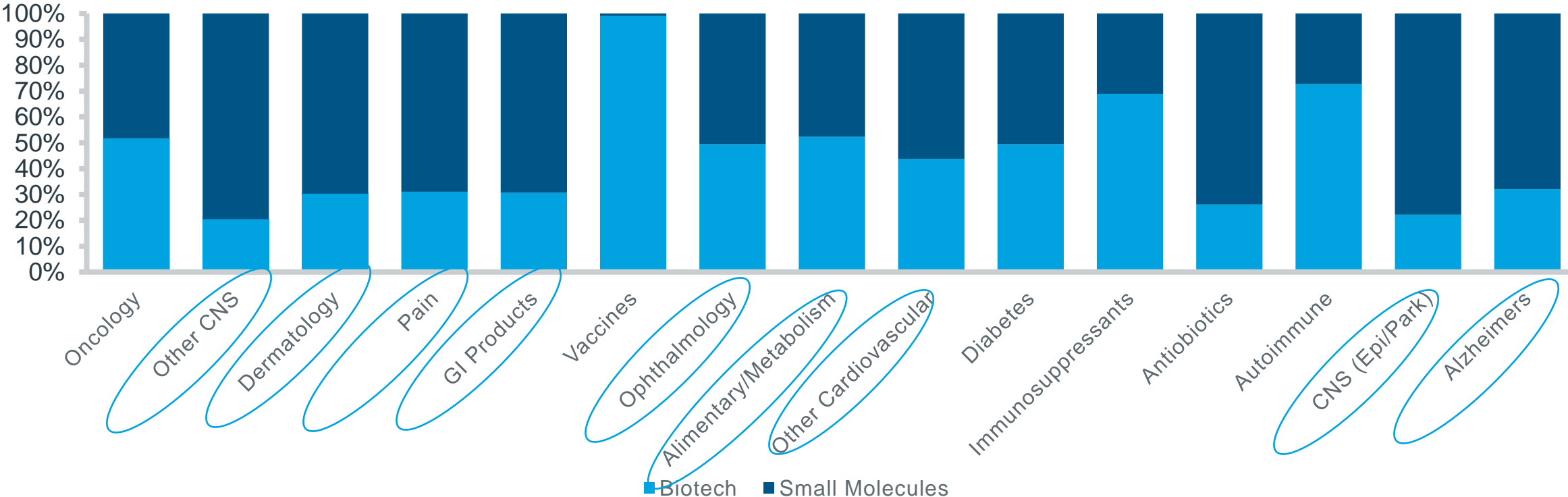
Real Net per Capita Medicine Spending and Growth by Product Type US\$



Source: IQVIA, National Sales Perspectives, IQVIA Institute, Jan 2019; U.S. Census Bureau; U.S. Bureau of Economic Analysis (BEA), Dec 2018

Biologics are in development in most therapy areas, including those traditionally based on small molecules

Share of late-stage R&D pipeline activity by molecule type



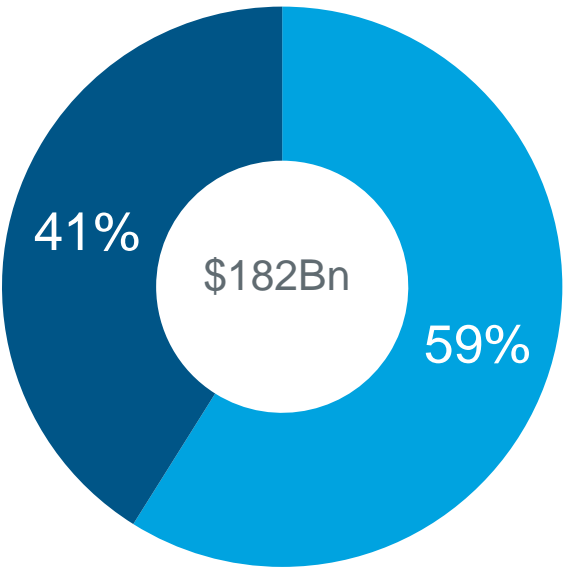
Source: IQVIA Pipeline Intelligence, Dec 2019

Biologics reach the market through multiple channels and paytypes, each with distinct payment characteristics

Medicare is 35% overall; Medicaid 22%; Commercial 42%, Cash 1%

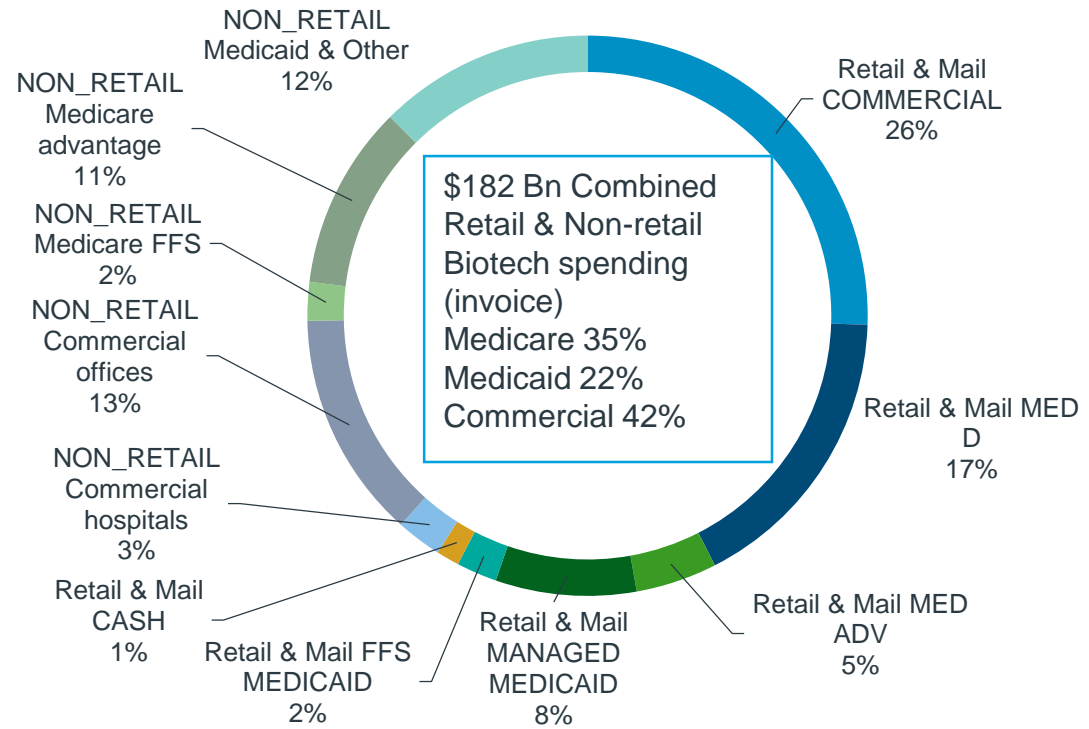
DIRECTIONAL ESTIMATES

US Biotech Market (Invoice Price level)



■ Retail & Mail ■ Non-retail

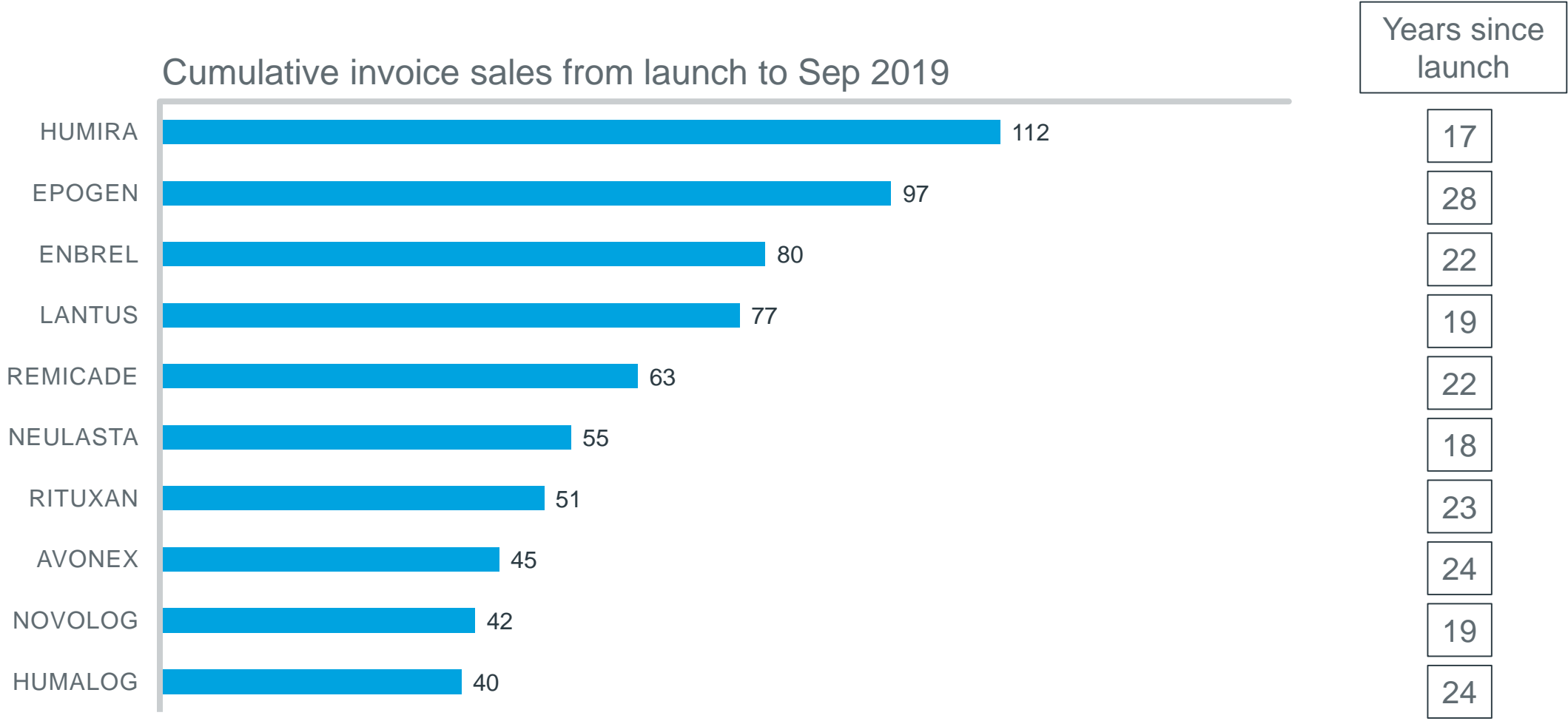
US Biotech Market All Channels Paytype Breakout Estimates



\$182 Bn Combined Retail & Non-retail Biotech spending (invoice)
 Medicare 35%
 Medicaid 22%
 Commercial 42%

Source: IQVIA Institute for Human Data Science, Feb 2020

The top 10 biologics each has cumulative sales of more than \$40 billion since launch and been on the market more than 17 years



Source: IQVIA National Sales Perspectives, Launch Edition Sep 2019

About 40% of small molecule market sales are accessible to generics, and generic efficiency remains flat at 97%

Percent of Small Molecule Sales Accessible to Generics and Generic Efficiency, 2014–2019

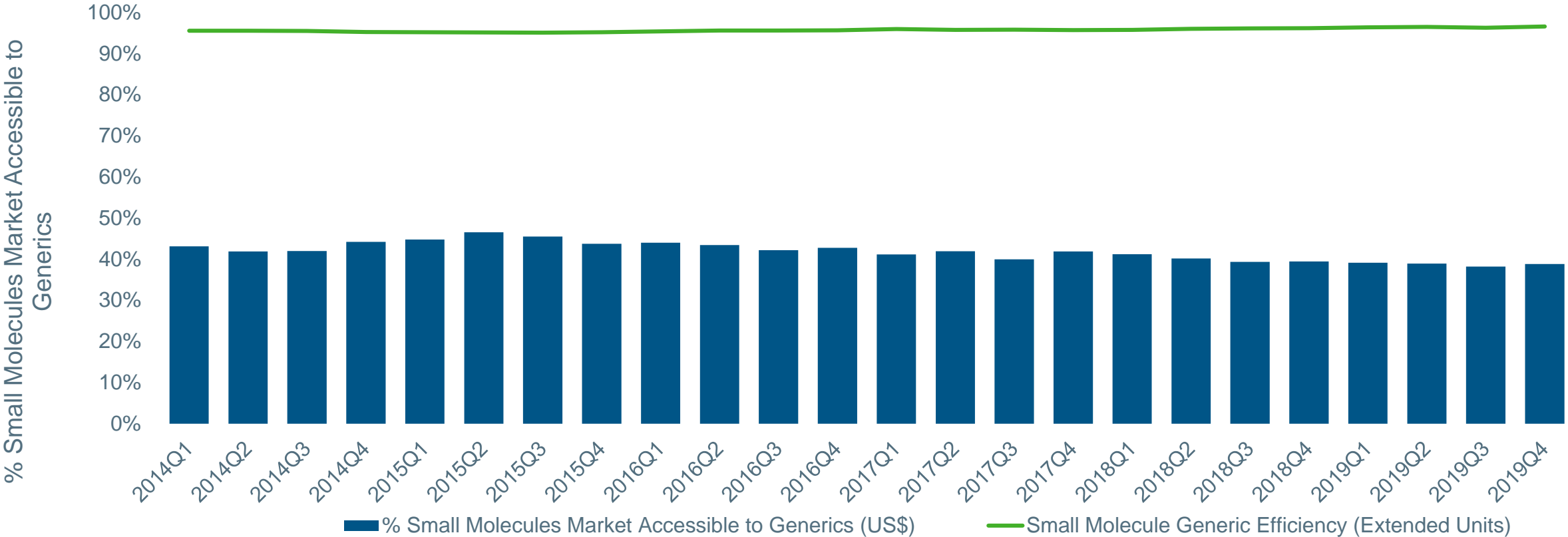


Chart notes: “Generic efficiency” measures share of market where generics are approved and launched

Source: IQVIA National Sales Perspectives, Dec 2019

By year-end 2019, 17% of the biologics market is accessible to biosimilars, and biosimilars have achieved 20% share

Percent of Biologics Sales Accessible to Biosimilars and Biosimilar Efficiency, 2013–2019

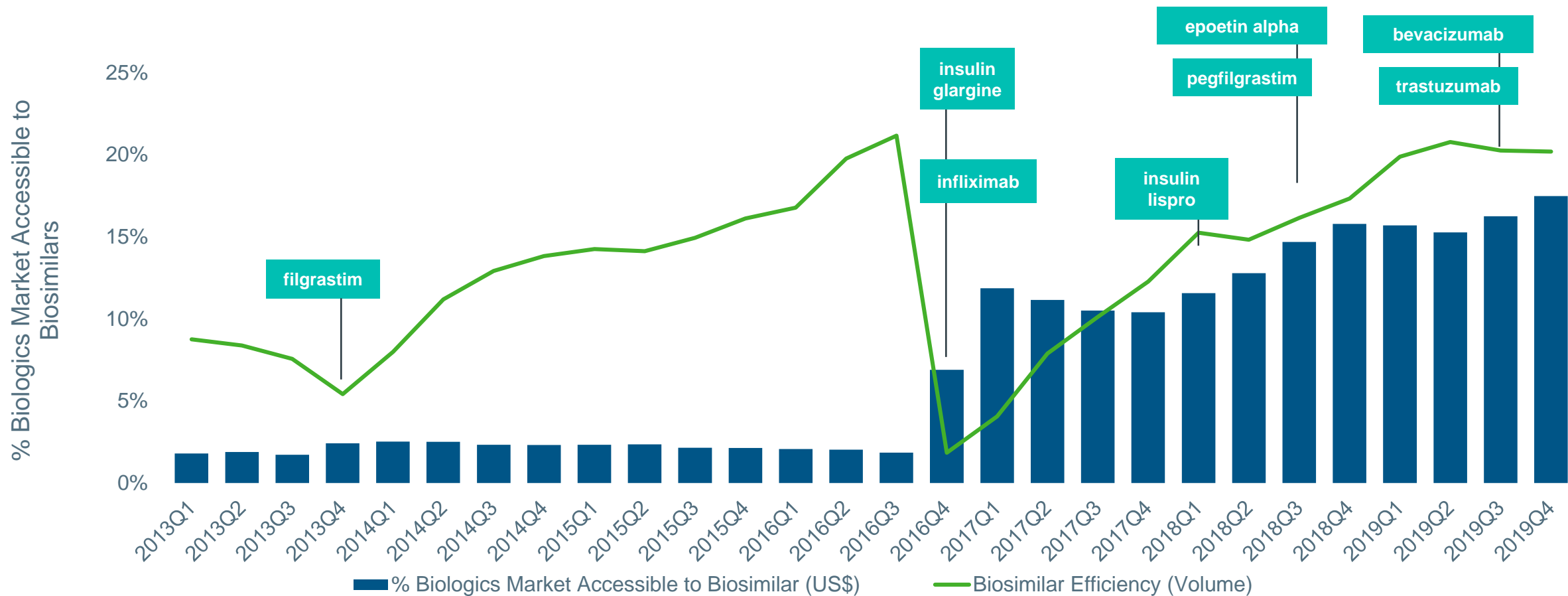


Chart notes: Chart includes 'biosimilars' as non-original molecules for medicines even if approved outside the 351(k) biosimilar pathway; "Biosimilar efficiency" measures share of market where biosimilars are approved and launched

Source: IQVIA National Sales Perspectives, Dec 2019

Including approved but not yet launched biosimilars, 50% of biologic market sales could face biosimilar competition

Percent of Biologics Sales Accessible to Approved and Launched Biosimilars and Biosimilar Efficiency, 2013–2019

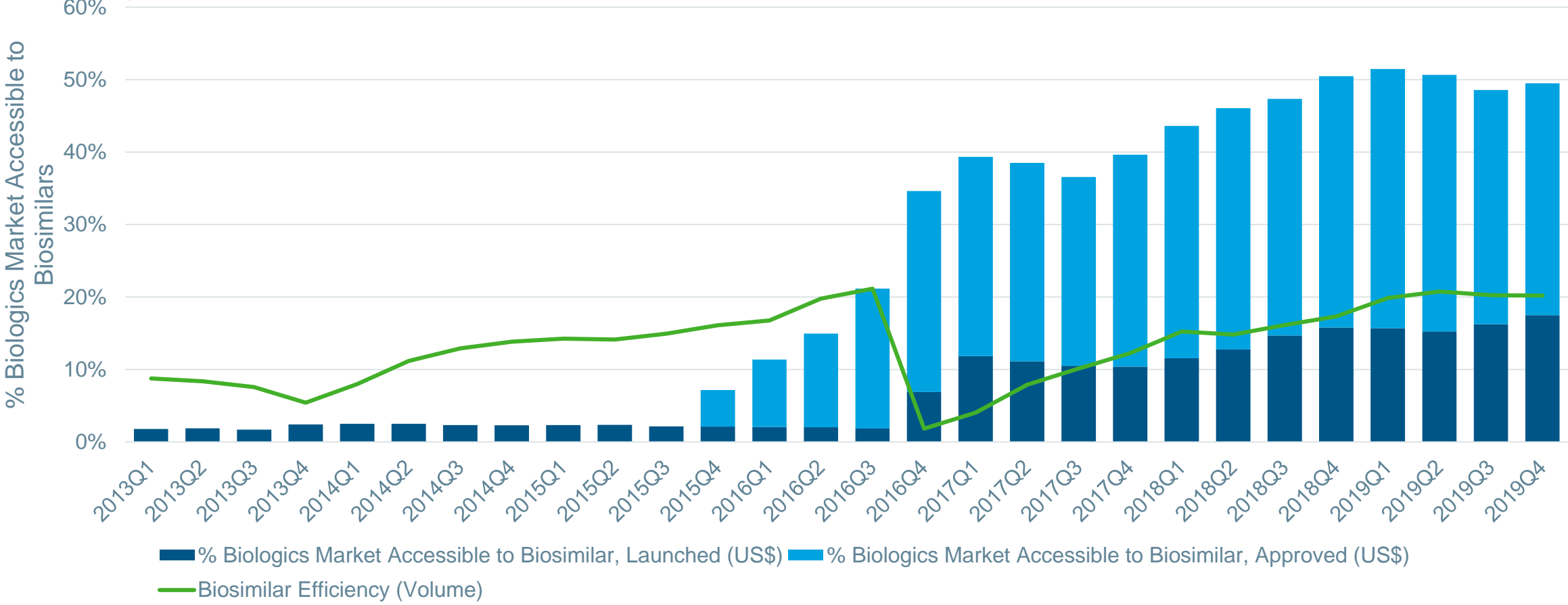


Chart notes: Chart includes 'biosimilars' as non-original molecules for medicines even if approved outside the 351(k) biosimilar pathway; "Biosimilar efficiency" measures share of market where biosimilars are approved and launched
 Source: IQVIA National Sales Perspectives, Dec 2019



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