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PharmaPoint

CANGRELOR (ACUTE CORONARY SYNDROME) - FORECAST AND MARKET ANALYSIS TO 2023

Executive Summary

The table below provides a summary of the key metrics for Cangrelor in the 7MM for Acute Coronary Syndrome (ACS) in the final forecast year, 2023.

Cangrelor: Key Metrics in the 7MM for Acute Coronary Syndrome in 2023	
Key Events (2013–2023)	**Level of Impact**
Launch of Cangrelor in the US and Japan in 2018 and in 5EU in 2015	↑↑
2023 Market Sales	
US	$96.0m
5EU	$22.5m
Japan	$4.4m
Global*	**$123.1m**

Source: GlobalData
Global = US, France, Germany, Italy, Spain, UK, Japan; 5EU = France, Germany, Italy, Spain, and UK; 7MM = US, 5EU and Japan; N/A= Not Available

Sales for Cangrelor in the Global Acute Coronary Syndrome Market

Cangrelor sales are expected to increase from $2.9 million upon launch in 2015 to $123.1 million in 2023.
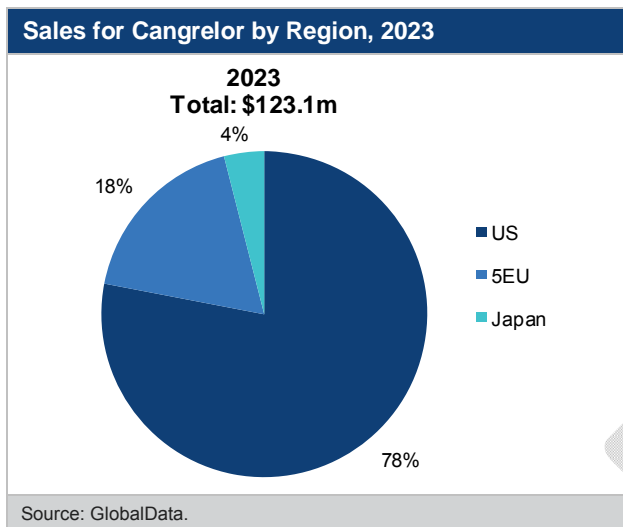
Major growth drivers for Cangrelor in the Acute Coronary Syndrome market over the forecast period include:

- Unlike marketed oral $P2Y_{12}$ inhibitors, cangrelor is an intravenous drug that has a very rapid onset and an exceptionally short half-life, allowing for unparalleled control of clotting by the physician.

- Data from the Phase II BRIDGE study supports use for bridging the period between cessation of other blood-thinning therapy and coronary artery bypass graft (CABG) surgery.

- Conversely, the major barrier for the growth of Cangrelor in the Acute Coronary Syndrome market includes:

- Two of the three pivotal CHAMPION Phase III studies were terminated due to their failure to show superiority to clopidogrel (CHAMPION PCI study) or placebo (CHAMPION PLATFORM study).

- Clopidogrel is well established and is known to be as efficacious as cangrelor in the CHAMPION PCI study.

- The market is already crowded with several other new ACS-indicated blood thinners, available in the US, Japan, and the five major EU markets, including Brilinta (ticagrelor) and Effient (prasugrel).

- Cangrelor must be administered intravenously.

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- The figure below illustrates Cangrelor sales in the 7MM by region during the forecast period.

Sales for Cangrelor by Region, 2023

**2023
Total: $123.1m**

4%
18%
78%

- US
- 5EU
- Japan

Source: GlobalData.

What Do the Physicians Think?

GlobalData KOLs anticipate that the incidence of ACS events is likely to increase in the coming years, primarily stemming from an aging population and advances in the ability to detect the diagnostic biomarker, cardiac troponin (cTn). The KOLs feel that the impact will be greatest on the incidence of non-ST-segment elevation acute coronary syndrome (NSTE-ACS).

"So, I anticipate that the number of heart attacks is going to go up. Because we are going to pick up a lot of very small ones, and probably, the FDA will approve the high sensitivity troponin test sometime within the next year or two for the US, and then there will be an increase in the number of patients with small heart attacks. And they will be candidates for cath [catheterization] and probably angioplasty…beta blockers, statins, the ACE [angiotensin converting enzyme] inhibitors, and ARBs [angiotensin receptor blockers]…down the line."

US Key Opinion Leader

"I think the trend that we're seeing, which is probably similar to most of the places in the western world, is a kind of increase in the people presenting with non-ST-elevation MI [myocardial infarction], kind of consistent with an aging population. And STEMI [ST-segment elevation myocardial infarction] rates are – I don't know – probably either going down a bit, or are about the same. They're certainly, not really increasing."

OUS Key Opinion Leader

GlobalData KOLs agree that the current ACS drug market is crowded and contains good options for ACS treatment. Additionally, they believe that new drugs will have to improve upon existing therapies to achieve clinical uptake. Further, GlobalData KOLs anticipate a lag in physician uptake of new ACS treatments, accounting for the time it takes to penetrate the clinic, build physician familiarity, and

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establish a solid foundation of clinical trial data for which to build an argument for replacing existing therapies. Lastly, some KOLs are frustrated that the industry is not investing more time in the areas with profound unmet needs, such as chronic heart failure.

"I don't know any particular drugs that have serious drawbacks in the practice of acute coronary syndrome at this time, including aspirin [acetylsalicylic acid], statins, and beta blockers, and ACE inhibitors. Almost all of them are safe. I don't see any immediate drawbacks for those drugs."

OUS Key Opinion Leader

"But, you know, no matter how good things are, there is a lag [in the uptake of a new drug]. So, if you look at the statins that didn't have data [early on, after they first launched], then a lot of statins were on large trials. It took many years before 50% of the people who should have been taking [statins], were taking it. Look at ACE inhibitors…it took almost a decade before 60–70% of people who should have been getting them, were getting them. There's a tremendous lag. Maybe things are a bit different this time, but no matter how good it [a new drug] is, I think it's [going to experience] slow uptake."

US Key Opinion Leader

"I think we really need data before you are going to do the secondary prevention long-term with these [factor] Xa inhibitors."

US Key Opinion Leader

"Until they have event data – and I have heard from the FDA that they [the PCSK9 mAbs] are not going to require event data to get approval – they may, I think, for all these drugs in a crowded market, they will probably end up doing an event study."

US Key Opinion Leader

"I am just really amazed by how much the market is crowded and how much industry is ready to invest into this area [antithrombotics], which is nonsense, which is absolute nonsense. Because, at the same time, the unmet need – and this is my heart failure background – is acute heart failure! I mean, you have got a 5–10% event rate. After acute coronary syndrome, you have got 50%!"

OUS Key Opinion Leader

GlobalData KOLs believe that there are still a large number of serious unmet needs in the ACS treatment space. One frustration that KOLs identify, time and again, is a perception in the clinic that major pharmaceutical companies are not focusing on the most pressing issues they face in the modern-day treatment of ACS (see above and below).

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"We still see a lot of people coming back with recurrent events. …Up to a third of people are coming back within a year with recurrent events, and that is a high proportion, and there is clearly a need to try and tamp down the inflammatory effects in these plaques, and so [for] new agents that specifically do that, I think there's a big role for them in the future."

OUS Key Opinion Leader

"There is still a large potential for healing agents. In order to repair the myocardial infarct, especially large infarcts with large scars and heart failure, some regenerative medicine is being tested, so this may be one way. But there are some anti-fibrotic agents that may still be useful in this area. So, it's a small subset, maybe 10 or 15% of patients with acute coronary syndrome, who end up by still having a very large infarct – whether they come late or they cannot be reperfused, or the reperfusion doesn't work – but they still have a large infarct and they end up having remodeling, enlarged hearts, and heart failure down the road, so these patients are still a large unmet need. They still have very high fatality rates and morbidity rates."

OUS Key Opinion Leader

"One limitation that we have now, that is not addressed usually in drug companies, is that in patients with STEMI, we will treat with primary angioplasty, it is frequent to have an epicardial restoration of the blood, of the flow in the epicardial vessel, but there is a problem in the restoration [of blood flow] in microvasculature. So, I think that…the drug companies are maybe too passive to this problem that is very important for us. So, we would need some drugs that improve – administered maybe by the catheter, by intracoronary catheter – to improve the distal microvasculature. That might improve the restoration of the left ventricular function. So, I think this is a field for improvement. …Not the big companies. No, because this is difficult, but the big companies are investing a lot of money in some fields that are difficult to obtain any benefit – in terms of new antiplatelet therapies and lipid lowering therapies. But, I think the important companies are not investing in this type of [research]."

OUS Key Opinion Leader

"Just because we can see that it's the future [post-ACS heart failure]. I think drugs that are going to help us with heart failure patients are going to be big sellers."

US Key Opinion Leader

"The future is brilliant."

OUS Key Opinion Leader

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2.1 Catalyst

Acute coronary syndrome (ACS) is the number one killer, worldwide. Given the extant armamentarium of cardio drugs, which boasts a vast array of treatments that confront the disease from multiple angles – from the myriad blood thinners to lipid-controlling agents and antihypertensive therapies – the fact that ACS remains the greatest scourge among non-communicable diseases on the planet, is telling. Modern cardiovascular research has revealed that the successful control of several key factors, such as blood lipid levels (particularly, low-density lipoprotein cholesterol [LDL-C]) and thrombosis, can greatly reduce the risk of occurrence of an ACS event. However, the prevention of incident ACS still stands as an immense challenge to the medical community. Additionally, the challenge of preventing repeat events, such as recurrent myocardial infarction (MI) and worsening angina, is still a nagging problem facing ACS treatment.

In this report, GlobalData highlights the major pharmaceutical players in both the current and future ACS treatment space who address these critical problems. Established drugs, such as the statins, the major antiplatelet agents, and the standard-of-care antihypertensives including the beta blockers and renin-angiotensin-aldosterone system (RAAS) inhibitors, represent the current state-of-the-art options in ACS treatment. For drugs in the late-stage pipeline, which include next-generation antithrombotic agents and novel therapies to treat low-density lipoprotein/high-density lipoprotein cholesterol (LDL/HDL-C), GlobalData's analysis will reveal how these new agents confront the challenges posed by the important unmet needs discussed above. Lastly, this report will highlight the key frontiers at the cutting edge of cardiovascular research, which include areas that the pipeline drugs themselves do not yet sufficiently address.

The current ACS therapeutic space is crowded and contains several classes of well-established drugs – statins and beta blockers, for example – that are thoroughly entrenched in the ACS treatment landscape. Not surprisingly, many of these main-stays of ACS drug therapy are now widely genericized, a fact that presents a challenging barrier for new entrants to the market. As a result, the pipeline therapies forecast here have been designed to approach the treatment of major ACS pathologies in novel ways. By exploiting new approaches to treat important problems, several drugs in the ACS pipeline have the potential to dramatically alter the ACS market. As such, it is possible that the global ACS market could more-than triple in size within the next ten years. The

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major drivers fueling this expansion will be the entrance of biologics, the PCSK9 (proprotein convertase subtilisin/kexin type 9) inhibitors, into the long-term LDL-C treatment space, a key market segment historically dominated by the statins. Additionally, new antithrombotic agents, such as Xarelto and Zontivity, are expected to carve out a niche in the post-ACS blood thinning market, resulting in a strong potential to reap blockbuster-level sales. Interestingly, as these late-stage pipeline drugs launch, the barrier for entry into the traditional ACS market segments will become considerably higher. This is likely to force future players to exploit the orphan drug targets, pathways, and pathologies, the results of which will represent an important shift in the historical trajectory of this large and lucrative market.

2.2 Related Reports

- GlobalData (2014). Type 2 Diabetes – Global Drug Forecast and Market Analysis to 2022, January 2014, PHARMADPP37964

- GlobalData (2013). Microvascular Complications of Diabetes – Global Drug Forecast and Market Analysis to 2022, December 2013, PHARMADPP37571

- GlobalData (2013). Acute Ischemic Stroke – Opportunity Analysis and Forecasts to 2017, December 2013, PHARMADOA37069

- GlobalData (2013). Obesity – Global Drug Forecast and Market Analysis to 2022, October 2013, PHARMADPP36385

- GlobalData (2013). Diabetic Foot Ulcers – Opportunity Analysis and Forecasts to 2017, October 2013, PHARMADOA36306

- GlobalData (2013). Chronic Heart Failure – Global Drug Forecast and Market Analysis to 2022, June 2013, PHARMADPP34543

- Global Data (2014). Acute Coronary Syndrome – Global Drug Forecast and Market Analysis to 2023, July 2014, GDHC69PIDR

- GlobalData (2014). Acute Coronary Syndrome – US Drug Forecast and Market Analysis to 2023, July 2014, GDHC246CFR

- GlobalData (2014). Acute Coronary Syndrome – 5EU Drug Forecast and Market Analysis to 2023, July 2014, GDHC247CFR

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- GlobalData (2014). Acute Coronary Syndrome – Japan Drug Forecast and Market Analysis to 2023, July 2014, GDHC248CFR

- GlobalData (2014). Brilinta (Acute Coronary Syndrome) – Forecast and Market Analysis to 2023. July 2014, GDHC432DFR

- GlobalData (2014). Effient (Acute Coronary Syndrome) – Forecast and Market Analysis to 2023. July 2014, GDHC433DFR

- GlobalData (2014). Crestor (Acute Coronary Syndrome) – Forecast and Market Analysis to 2023. July 2014, GDHC434DFR

- GlobalData (2014). Xarelto (Acute Coronary Syndrome) – Forecast and Market Analysis to 2023. July 2014, GDHC435DFR

- GlobalData (2014). Angiomax (Acute Coronary Syndrome) – Forecast and Market Analysis to 2023. July 2014, GDHC436DFR

- GlobalData (2014). Zontivity (Acute Coronary Syndrome) – Forecast and Market Analysis to 2023. July 2014, GDHC438DFR

- GlobalData (2014). Alirocumab (Acute Coronary Syndrome) – Forecast and Market Analysis to 2023. July 2014, GDHC439DFR

- GlobalData (2014). Evolocumab (Acute Coronary Syndrome) – Forecast and Market Analysis to 2023. July 2014, GDHC440DFR

- GlobalData (2014). Bococizumab (Acute Coronary Syndrome) – Forecast and Market Analysis to 2023. July 2014, GDHC441DFR

- GlobalData (2014). Anacetrapib (Acute Coronary Syndrome) – Forecast and Market Analysis to 2023. July 2014, GDHC442DFR

- GlobalData (2014). Evacetrapib (Acute Coronary Syndrome) – Forecast and Market Analysis to 2023. July 2014, GDHC443DFR

- GlobalData (2014). Acute Coronary Syndrome – Current and Future Players. July 2014, GDHC1036FPR

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2.3   Upcoming Related Reports

- Global Data (2014). Atrial Fibrillation – Global Drug Forecast and Market Analysis to 2023, August 2014, GDHC87PIDR

- GlobalData (2014). Dyslipidemia – Global Drug Forecast and Market Analysis to 2023, October 2014 GDHC46PIDR

Appendix

9.7   About GlobalData

GlobalData is a leading global provider of business intelligence in the healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports, and forecasts. Our analysis is supported by a 24/7 client support and analyst team.

GlobalData has offices in New York, San Francisco, Boston, London, India, Korea, Japan, Singapore, and Australia.

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