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CASE STUDIES

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FAIR AND RESPONSIBLE DRUG PRICING: A CASE STUDY OF RADIUS HEALTH AND *ABALOPARATIDE*

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We examine the disruptive pricing strategy of abaloparatide, an osteoporosis drug launched by Radius Health in 2017 at a list price 45% lower than its main competitor. This strategy allowed Radius to gain rapid access to this market and achieve a corresponding growth in patient volume. It now faces two challenges: the perverse incentive of Medicare Part D rebates, and the paradox of coverage structure that prevents lower list prices from necessarily leading to lower out-of-pocket costs for all patients. Nevertheless, this pricing strategy is sustainable for the drug manufacturer, beneficial for the patient, and may have potential applications in other therapeutic areas.

1 Introduction

The healthcare industry in the United States (U.S.) is a complex ecosystem with many different stakeholders. Unlike the universal single-payer healthcare systems of many European countries, the accessibility of prescription drugs in the U.S. is largely determined by contract negotiations between health plans and drug manufacturers about formulary placement. These negotiations can sometimes result in higher out-of-pocket costs for the patient, since the current structure of the U.S. healthcare system creates a perverse incentive for many health plans to elicit higher rebates from drug manufacturers in exchange for formulary placement of brand-name drugs, thereby increasing patients' out-of-pocket costs.

Despite the landmark reforms of the Affordable Care Act, 28% of adults in the U.S. between the ages of 19 and 64 with full-year

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health insurance in 2016 were still underinsured, and unable to afford prescribed medication. This is more than twice the corresponding rate in 2003 (Collins *et al.*, 2017). The high list price of drugs exerts a direct adverse impact on adherence rates and patient treatment outcomes, especially for patients who have not reached their insurance deductible or who make a coinsurance payment at a fixed percentage of the list price. Similarly, a 2010 study found that prescription drugs with a copayment over $50 are nearly five times more likely to be abandoned by the patient at the pharmacy counter than those with no copayment (Shrank *et al.*, 2010). These high list prices not only impose significant financial burdens on individual patients, but also threaten the public health of general society.

In its healthcare blueprint, "American Patients First," issued in May 2018, the Trump administration identified high list prices and high out-of-pocket costs of drugs as two major challenges to the U.S. healthcare system (U.S. Department of Health & Human Services, 2018). To directly reduce the out-of-pocket costs to patients, the Department of Health and Human Services proposed in January 2019 to replace the rebate-driven system with upfront discounts (U.S. Department of Health & Human Services, 2019). However, as the U.S. healthcare system consists of hundreds of widely varying local systems, there are considerable challenges to regulating drug prices at the federal level. In the absence of effective government regulation, the pharmaceutical industry can benefit from fair and responsible pricing strategies that are both financially sustainable for the drug manufacturer and affordable for patients with standard health insurance.

In this case study, we analyze Radius Health's pricing strategy for the drug abaloparatide, approved by the U.S. Food & Drug Administration (FDA) in 2017 to treat postmenopausal women with osteoporosis at high risk of fracture. With an initial list price 45% lower than its main competitor, abaloparatide managed to achieve rapid market access and significant patient volume growth within 20 months after launch. We discuss the potential of this pricing strategy to become a template for responsible pricing in the pharmaceutical industry.

2 Background

The success of Radius Health's pricing strategy is highly specific to the context of anabolic osteoporosis, as are the challenges to it. To understand why its pricing strategy has disrupted the osteoporosis therapeutics market, it is essential to first examine the disease and patient population of osteoporosis, and its market dynamics prior to the launch of abaloparatide in 2017.

Women's osteoporosis is a common but largely undertreated disease in the U.S. As of 2010, an estimated 8.2 million women above the age of 50 years in the U.S. suffered from osteoporosis (Wright *et al.*, 2014). A study in 2014 found that, among a group of 47,171 women over the age of 50 who had experienced an osteoporotic fracture, only 23% of them received treatments for osteoporosis during the first year following the fracture (Wilk *et al.*, 2014). Because many osteoporosis patients also have other chronic conditions (e.g., cardiovascular disease), they tend not to take adequate measures to prevent fractures, especially if the medication incurs a serious financial burden. Once an osteoporosis patient experiences a fracture, however, the treatment is often much more expensive than the preventive medication, and the patient is subject to an increased risk of mortality due to associated complications from the fracture (Cummings and Melton, 2002).

Currently there are two major categories of treatment for women's osteoporosis: antiresorptive agents and anabolic agents. Antiresorptive agents

reduce the rate of bone breakdown, have lower costs, and are administered orally or via injection. Anabolic agents, on the other hand, stimulate the formation of new bones, but have a much higher cost, and require daily self-injection (Black and Rosen, 2016).

In 2016, the antiresorptive drug denosumab was the revenue leader in women's osteoporosis, treating 800,000 patients, and capturing all annual growth in patient volume. In comparison, the anabolic agent segment of the market treated only 48,000 patients in 2016, a market penetration of less than 5%. The patient volume within this segment declined by 45% from 2011 to 2016, largely due to a 250% increase in the list price of teriparatide, the only anabolic drug available between 2003 and the launch of abaloparatide in 2017. This price increase appears to reflect the lack of long-term commitment of the manufacturer Eli Lilly in the women's osteoporosis market. At the time of the increase, Lilly's patent on teriparatide was expected to expire by August 2019 (Derbyshire, 2018). The downturn of the anabolic agent market coupled with looming competition from biosimilar versions of teriparatide sets the stage for Radius Health's disruptive pricing strategy for abaloparatide.

3 Company history

Radius Health, Inc. is a biopharmaceutical company based in Waltham, Massachusetts. Originally named Nuvios, it was founded in 2003 by a group of academic researchers specializing in endocrinology and bone mineral metabolism with a primary focus on research and development (R&D). In 2005 Radius in-licensed the compound abaloparatide, receiving the patent license from the pharmaceutical firm Ipsen to develop a novel anabolic drug for osteoporosis. One year later, Radius in-licensed the compound elacestrant from Eisai to initiate the development of a new hormone therapy for late-stage ER+/HER2- breast cancer.

As the clinical program for abaloparatide (administered as a subcutaneous injection) progressed to phase 3 in 2011, Radius decided not to partner with a major pharmaceutical company to launch its lead product for the U.S. market, but instead launched abaloparatide on its own. In its transition from an R&D firm to a commercial company, Radius completed its initial public offering in June 2014, greatly expanded its sales and marketing departments, and brought onto its senior management team new members with extensive expertise in drug development and commercialization. In April 2017, abaloparatide was approved by the FDA to treat postmenopausal women with osteoporosis at high risk of fracture.

Radius Health intends to become a leader in women's health therapeutics in the U.S. Its current pipeline includes a novel transdermal patch formulation of abaloparatide (currently in phase 3 clinical trials), abaloparatide therapy for men with osteoporosis (phase 3), and the hormone therapy elacestrant for late-stage ER+ and HER2- breast cancers (phase 3). The primary focus of its mission is to bring innovative and financially accessible therapies to women with serious health conditions.

4 Pricing strategy of abaloparatide

Radius's pricing strategy for its lead product, abaloparatide, was developed under the realization that it would need to achieve high sales and rapid gains in market share in order to meet the goals of its stakeholders. Launched in June 2017, abaloparatide faced intense competition from the anabolic drug teriparatide, manufactured by Eli Lilly since 2002 and covered by the major health plans. Radius believed that a lower list price would help to accelerate the

coverage of abaloparatide by commercial health plans, Medicaid, and Medicare Part D.

Radius anticipated future competition from biosimilar versions of teriparatide. Following the expiration of the patent for teriparatide in the second half of 2019 (Derbyshire, 2018), it was projected that biosimilar drugs would enter the anabolic agent market with list prices 15–30% lower than that of teriparatide. However, abaloparatide with a list price 45% lower than that of teriparatide should still retain a competitive edge in pricing after the entrance of these biosimilar drugs.

Radius also wanted to enlarge the market for anabolic therapies for osteoporosis. As described earlier, the patient volume of this market had declined by over 45% from 2011 to 2016, largely due to the 250% increase in the list price of teriparatide to $35,000 annually. A significantly lower list price would quickly differentiate abaloparatide as a product and provide a strong incentive for physicians to prescribe it as the preferred anabolic therapy.

In addition, Radius wanted to demonstrate its commitment to socially responsible drug pricing. Price spikes taken by brand-name drugs, often near the expiration of their patents, have generated intense public criticism of the ethics of the biopharmaceutical industry. Instead of creating a niche product with a high price and a small patient volume, Radius believed that a lower price for abaloparatide would make a state-of-the-art anabolic therapy accessible to a larger patient group.

4.1 Success

The first milestone of Radius's pricing strategy was to gain coverage among the commercial and Medicaid segments of the health plan market. Within eight months of approval, abaloparatide achieved 92% coverage of patients insured by the commercial health plan market. After 20 months, it had achieved 99% coverage in the commercial market, and 96% in Medicaid, both exceeding the coverage of its main competitor. This milestone was significant, since the commercial and Medicaid segments combined account for 50% of the volume of the anabolic agent market, and 81% of total coverage in the U.S.

By the end of 2018, abaloparatide had captured 40% of new-to-brand prescriptions in the anabolic agent market, 31% of new prescriptions, and 27% of total prescriptions, as measured by patients' months on therapy (PMOT). As of 2019, abaloparatide is covered at parity or better by five of the seven largest Medicare Part D health plans in the U.S., an increase of 28% in potential anabolic agent market volume, and as of the third quarter of 2019, abaloparatide has captured 42% of new prescriptions and 37% of total prescriptions.

It is important to Radius's pricing strategy not only to expand its share of the anabolic agent market, but also to expand its patient volume as well. The patient volume, again measured by PMOT, grew by 8.5%, on average, during each quarter of 2018 over the same quarter in 2017. Presumably, its low list price and high coverage by commercial health insurance plans created an incentive for many physicians to prescribe abaloparatide as the preferred therapy over its anabolic and antiresorptive competitors.

In terms of revenue performance and projected future growth, Radius's pricing strategy has also been a success. Abaloparatide surpassed its revenue guidance of $95–$98 million domestic net sales in 2018, and updated its 2019 revenue guidance to $165–$170 million domestic net sales through October 2019. The pricing strategy of abaloparatide has proved to be financially sustainable to the drug manufacturer.

4.2 Challenges

However, the pricing strategy for abaloparatide also has encountered some challenges, most notably in expanding its Medicare Part D coverage. Twenty months after launch, abaloparatide has only achieved 67% coverage among Medicare Part D beneficiaries, compared to 94% coverage for teriparatide.

Abaloparatide's launch took place during the formulary review cycle of the Center of Medicare and Medicaid Services (CMS). This accident of timing was responsible for a delayed addition of abaloparatide to Part D formularies. This delay contributes to its low Part D coverage, but only in part. The current structure of the Medicare Part D program creates a perverse incentive for Part D health plans to favor drugs with higher list prices in exchange for higher rebates. During their initial formulary negotiations with Radius, some major health plans expressed concern over the financial disincentive caused by abaloparatide's lower list price. Other health plans, however, preferred abaloparatide, since it reduced the overall cost to the healthcare system.

Another challenge to Radius's pricing strategy is the uncomfortable fact that a lower list price does not necessarily lead to lower out-of-pocket costs for all patients. The out-of-pocket cost is set by multiple factors other than list price, including formulary tiers, copay and coinsurance payments, and insurance premiums. Even within the standard Medicare Part D plan, a patient may incur different levels of out-of-pocket costs at different phases of its coverage. For example, in the final catastrophic phase of Medicare Part D, abaloparatide has a 59% lower out-of-pocket cost than its main competitor. However, the out-of-pocket cost during the coverage gap before the catastrophic phase (the notorious "donut hole") is a heavy financial burden for many patients. Fifty percent of these patients will discontinue their treatments after seven months of their prescribed therapy, out of a recommended treatment period of 18 to 24 months.

Radius also faces new competition in the anabolic agent market. In addition to biosimilar versions of teriparatide potentially launching in the second half of 2019, Amgen's novel anabolic agent romosozumab received FDA approval on April 9, 2019. While the presence of more agents will likely increase the patient volume of the anabolic agent market, it also inevitably puts pressure on the market share of abaloparatide.

Finally, as a small biotech startup with a relatively short history of commercial experience, Radius faces pressure to build brand loyalty among healthcare practitioners and to establish itself as a trusted partner with health insurance payers. Its single-drug portfolio limits its pricing flexibility, since it must generate revenue to support future R&D and create returns to its investors.

4.3 Future evolution

The list price of abaloparatide increased by 5.9% on January 1, 2019. As of the time of submission of this article, biosimilar versions of teriparatide have not entered the U.S. market. The extent to which increasing competition will affect the market performance of abaloparatide remains to be seen. Radius Health, however, still remains committed to its socially responsible pricing strategy.

5 Conclusion

Abaloparatide was launched by Radius Health at a list price 45% lower than its main competitor. This disruptive pricing strategy was based on several key factors, including the increasingly competitive landscape for women's osteoporosis treatment, the decline in the market volume for anabolic therapies, and a commitment to

responsible drug pricing. Twenty months after its approval, abaloparatide has achieved nearly full coverage of the commercial and Medicaid segments of the U.S. health plan market, and over two-thirds of the Medicare Part D segment. It has captured a considerable share of the anabolic agent market, grown its patient volume, and caused Radius to exceed its revenue guidance to the benefit of future sales and the company's R&D budget. Its pricing strategy has so far proven to be financially sustainable.

However, several challenges to this pricing strategy remain. A lower list price may not necessarily lead to lower out-of-pocket costs for all patients due to the structure of their health insurance, such as the "donut hole" in coverage for Medicare Part D. As a result, many patients prematurely discontinue their treatments. There is also a financial disincentive to certain health plans to place a drug with lower list price onto their formularies, since the rebate the plans will receive is lower than those of competing drugs.

There is growing public concern over incentives to health plans to favor drugs with higher list prices and higher rebates. Recent healthcare reforms are intended to implement changes that create incentives for health plans to adopt drugs that are priced responsibly. For example, the Department of Health and Human Services recently proposed to replace the rebate system with upfront discounts in drug list price, although the details of the proposed implementation remain to be seen.

It should also be noted that pricing is not the ultimate factor that determines the success of a novel drug or therapy. A pharmaceutical company seldom achieves market leadership by underpricing its competitors, but rather by using its pricing strategy to facilitate translational biomedical research and to create innovative products with improved therapeutic outcomes and drug delivery technologies. Nevertheless, socially responsible drug pricing creates numerous positive spillovers, reducing the overall cost to the healthcare system and benefiting a large group of patients under standard health insurance plans, while establishing brand loyalty among healthcare stakeholders that is particularly important to young commercial biotech companies like Radius Health.

This case study of abaloparatide illustrates both the success and the challenges of a fair and responsible drug pricing strategy, and potential applications to many other therapeutic areas. With continued reform and medical innovation in the healthcare industry, this method of pricing may be one of the most effective ways to simultaneously maximize the revenue of a pharmaceutical company and benefits to the patients.

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Supplementary Materials

Biographies of Interviewees at Radius Health

Jose Carmona, Senior Vice President and Chief Financial Officer

Mr. Carmona joined Radius in May 2017. Prior to joining Radius, Mr. Carmona served as the Chief Financial Officer of Innocoll Holdings plc and its predecessor, Innocoll AG, from 2015 to 2017. Prior to that, he was Chief Financial Officer of Alcon Europe, Middle East & Africa, a division of Novartis AG, from 2013 to 2015 and held numerous financial management positions with increasing responsibility at Novartis from 2003 to 2013. Mr. Carmona received his B.S. in Industrial Civil Engineering from Universidad Tecnica Federico Santa Maria in Valparaiso, Chile, and his M.B.A. from Columbia Business School in New York City.

Brent Hatzis-Schoch, Senior Vice President and General Counsel

Mr. Hatzis-Schoch J.D. joined Radius in April 2015. Prior to joining Radius, Mr. Hatzis-Schoch was Senior Vice President and Chief Legal Counsel of Merz Pharma in Frankfurt, Germany from 2013 to 2015. Prior to Merz, Mr. Hatzis-Schoch served for five years as General Counsel to Agennix AG. He also held senior legal positions in European legal counsel for Baxter International, Associate General Counsel of Pharmacia Corporation, and General Counsel of GPC Biotech AG. Mr. Hatzis-Schoch holds a B.A. from the University of Delaware and J.D. from George Washington University.

Jesper Høiland, President and Chief Executive Officer

Mr. Høiland has served as President and CEO of Radius since July 2017. He has 30 years of experience in the biopharmaceutical industry with expertise in endocrinology and women's health. Prior to joining Radius, Mr. Høiland served as President of Novo Nordisk Inc. USA. Since he joined Novo Nordisk in 1987, Mr. Høiland held multiple global roles of increasing responsibility, including leading its International Operations which spanned 150 countries. Mr. Høiland is a member of the board of directors of LEO Pharma. He received his M.Sc. in Management from Copenhagen Business School in Denmark.

Deborah Kauffman, Senior Vice President, Human Resources

Ms. Kauffman joined Radius in 2015 as a Vice President to lead the Human Resources division as Radius embarked on its development and commercialization phase. Prior to that, Ms. Kauffman had various assignments in the pharmaceutical industry, including consulting roles. She served in various positions at AstraZeneca Pharmaceuticals, from 2001 to 2013, most notably as a Vice President of Human Resources (U.S.). She holds a B.A. from Franklin and Marshall College.

Joseph Kelly, Senior Vice President, Sales and Marketing

Mr. Kelly joined Radius in November 2017. Prior to joining Radius, Mr. Kelly was Vice President of Sales, South and East United States, at Novo Nordisk, Inc. From 2002 to 2017, Mr. Kelly served in various positions of increasing responsibility at Novo Nordisk, including commercial leadership roles. Mr. Kelly attended the University of Georgia and received his B.S. in Public Relations from Utica College of Syracuse University.

C. Richard Lyttle, PhD, Chairman, Scientific Advisory Board

Dr. Lyttle has served as Chairman of Scientific Advisory Board since June 2012. He was

President and CEO of Radius from 2004 to 2011 and interim Chief Scientific Officer from 2011 to 2012. Dr. Lyttle was Executive Chairman of Karos Pharmaceuticals from 2010 to 2013. Previously, he was Vice President of Discovery for Women's Health and Bone and Head of Women's Health Research Institute at Wyeth. Prior to that, Dr. Lyttle was Research Professor of Obstetrics, Gynecology, and Pharmacology at University of Pennsylvania. He received his PhD in Biochemistry from Queen's University, Kingston, Ontario and conducted postdoctoral research at Rockefeller University and University of Chicago.

Charles Morris, Chief Medical Officer

Mr. Morris, MBChB, MRCP, joined Radius in September 2018. Prior to joining Radius, Dr. Morris served as Chief Development Officer at PsiOxus Therapeutics, Ltd., since September 2016. Prior to PsiOxus, he was Chief Development Officer at ImmunoGen, Inc. from 2012 to 2016. Prior to that, Dr. Morris was Chief Medical Officer at Allos Therapeutics, Inc., and held leadership positions at Cephalon and AstraZeneca Pharmaceuticals (formerly Zeneca Pharmaceuticals). Dr. Morris is a graduate of Sheffield University Medical School and is a Member of the Royal College of Physicians of London.

Averi Price, Chief Compliance Officer

Ms. Price built the compliance program at Radius and helped prepare the company to launch its first commercial product. Prior to joining Radius, Ms. Price led a compliance team at Sunovion Pharmaceuticals Inc. to develop and execute the commercial, corporate and research and development compliance programs. Prior to her in-house pharmaceutical compliance experience, Ms. Price practiced at Boston-area law firms and represented various stakeholders in the healthcare industry. She holds a B.A. from the University of Chicago and a Law degree from University of Michigan.

Chhaya Shah, Senior Vice President, Technical Operations

Ms. Shah joined Radius in July 2018. Prior to joining Radius, Ms. Shah was the Senior Vice President of Manufacturing and Technical Operations at Synergy Pharmaceuticals. Prior to that, Ms. Shah served various functions at Shire Pharmaceuticals, where she was responsible for end-to-end supply chain for over 20 products, developed quality systems and supported global approval of multiple products. Before joining Shire, Ms. Shah held various compliance, quality assurance and manufacturing leadership roles at Wyeth Pharmaceuticals, Vaccine Division and Abbott Laboratories.