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Memo

Date: April 14, 2014

To: Mark Timney, Russ Gasdia

From: Cam McClearn, [redacted]

Subject: Targiniq ER Strategic Assessment and Recommendations

During the past two months, Monitor Deloitte has conducted an assessment of Targiniq ER's strategic opportunities in the U.S. We took an exhaustive look at Purdue's options for the asset using our industry-proven, and analytically rigorous, strategy development approach. We grouped Targiniq ER's options into two categories:

- **Offensive:** Launching Targiniq ER in the market to complement the existing Purdue pain portfolio and drive additional market share by serving an unmet market need

- **Defensive:** Launching Targiniq ER to defend Purdue's position against future branded competitors and / or the eventual threat of generic OxyContin

Based on this assessment, we believe it unwise for Purdue to launch Targiniq ER as either an offensive or defensive play. This memo outlines our analysis and recommendations and accompanies the PowerPoint document entitled *Targiniq ER Strategic Assessment Board Pre-Read,* dated April 14, 2014.

The Launch Environment: ERO Market Context

Targiniq ER would launch into a very challenging market environment. The $5.0 Billion Extended Release Opioid (ERO) market has been steadily shrinking in value as more generics enter the market and prescriptions have remained stable. Purdue products have 76% of the branded ERO market, led by OxyContin with a 69% share.

There are abuse deterrence formulation (ADF) benefits of Targiniq ER that do offer some differentiation, however, abuse deterrence as a product attribute has yet to drive behavioral change with physicians and payers. Physicians recognize the importance of abuse deterrence mechanisms, but either see limited applicability to their individual patient populations or see no gaps in existing ADF options. Payers remain highly cost-focused and have not demonstrated a willingness to pay extra for ADF of any type. Additionally, there is no expressed preference for or regulatory directive that advantages chemical over physical ADF technologies which would benefit Targiniq ER.

While the expected OIC indication would provide some additional differentiation, the expected 2017 OIC indication appears to be at risk given continued challenges in the clinical trial program.

The ERO market is expected to change dramatically when OxyContin loses its patent protection. It faces constant threat from generic manufacturers who may launch at risk prior to the brand's loss of exclusivity (LOE). When generics enter, the market will lose the majority of its value within approximately 6-9 months. Theoretically, this market event could provide some opportunity for another branded agent like Targiniq ER. With its lack of differentiation, however, Targiniq ER would instead compete for the fraction (approximately 10% of original market size by value) of the market served by branded agents. Targiniq ER has virtually the same LOE timeline as OxyContin (2021 and 2020, respectively), so it does not offer a meaningful extension of Purdue's portfolio of patent-protected products.

Finally, the market conditions and expected U.S. label, offer unique challenges to Targiniq ER vis-à-vis other Purdue markets. For example, Targin has had some market success in Germany, however, OxyContin had a much smaller share of the ERO market enabling Targin to launch broadly without serious concern of cannibalization. Targin also launched with a stronger label (i.e. prevention of OIC) and enjoyed a favorable market access environment. These features will not be present in the U.S. for Targiniq ER.

Targiniq ER Offensive Launch Strategies

With this market landscape, and with the goal of limiting cannibalization of OxyContin, we have identified three opportunities.

1. **Abuse Deterrence**: Position Targiniq ER as an efficacious ERO with a chemical abuse deterrence mechanism. Targiniq ER would be targeted at those physicians who are limited prescribers of OxyContin as there is a subset of physicians who value the efficacy of the oxycodone molecule, but avoid the OxyContin brand.

2. **Stepping Stone from IRO to ERO**: There are a significant number of patients currently eligible for an ERO, but remain on an IRO for a variety of reasons (e.g. lack of knowledge of appropriate use of IRO vs. ERO, physician concern about escalating dosages, etc.). Purdue could position Targiniq ER for this segment stressing the product's dose ceiling as an "exit strategy" to physicians otherwise hesitant to move appropriate patients to an ERO. An additional benefit of this strategy is that it would increase the overall size of the ERO market, by converting appropriate patients, thereby benefiting OxyContin.

3. **Opioid Induced Constipation (OIC) Focus**: Upon the successful receipt of the OIC indication, Purdue could position Targiniq ER as an ERO with OIC benefits in a single pill. The OIC indication is expected no earlier than 2017, however, so Targiniq ER would also compete with single agent OIC products set to enter the market before 2017, limiting its uniqueness and value.

We modeled these combined opportunities under two different, but realistic, scenarios. First, we modeled an upside scenario, which assumes relatively favorable conditions (e.g. ability to change entrenched physician behavior, limited cannibalization of OxyContin, superior sales execution, receipt of the OIC indication). Then, we prepared a downside scenario which factors in a less favorable, but not unlikely, set of assumptions (e.g. more limited behavior change among prescribers, greater access restrictions, less effective sales execution, greater cannibalization of OxyContin and no OIC indication).

In the upside scenario, Targiniq ER could generate $240 M in peak revenue, but operating income is negative until 2018 and NPV is negative ($53 M) over the period of its assumed patent life (2014-2022). The downside scenario predicts peak revenue of only $60 M in 2020 and an NPV of negative ($164 M) over its life.

Overall, these unfavorable NPVs are driven by the relatively limited revenue opportunity (i.e. niche focus to avoid OxyContin) and the high costs required to launch a new product in the current market (e.g. greater sales force, significant market access rebates, market development efforts specifically for the Stepping Stone strategy, etc.).

Targiniq ER Defensive Opportunities

The defensive opportunities for Targiniq ER are also limited. The branded products entering the market during the launch window are likely to focus on abuse deterrence as a point of differentiation. Because there is currently no data or regulatory guidance that advantages one technology over another, Targiniq ER's ADF properties will not be highly valued. In fact, OxyContin’s abuse deterrent mechanism is likely to be just as effective as Targiniq ER in defending against branded competitors.

Additionally, when OxyContin loses its patent protection, the value of the ERO market will shrink dramatically. Targiniq ER would not have meaningful, promotable clinical differentiation (with or without the OIC indication) that would justify a large price premium over generic OxyContin.

Other Strategic Considerations

There are several other important factors we have considered in our assessment of this opportunity:

- There will likely be market confusion, if not a negative reaction, among prescribers and the general public, if Purdue were to launch a product that is so substantially similar to OxyContin. The attention being paid to the opioid market in the U.S. is at an all-time high and therefore addressing true unmet needs is critical for success in the market.

- We believe each of the strategies we have identified above can be achieved with OxyContin with less distraction internally and in the market, and greater returns.

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Recommendation

It is therefore our recommendation that Purdue not launch Targiniq ER in the U.S. market.

As an offensive strategy Targiniq ER is unprofitable in both upside and downside scenarios given the limited market opportunity and high launch costs. As a defensive play, Targiniq ER has limited ability to defend Purdue’s market share against competitive and generic threats to OxyContin due to its limited differentiation.

In addition to being financially imprudent, we believe launching Targiniq ER would distract the Purdue organization from other initiatives and investments that could offer higher returns, including the current focus on the core brand, OxyContin, and better position the organization for the future.