Dr William Schmidt discusses how PF614 TAAP works – from the IASP World Congress

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The FDA has recognized the uniqueness of this particular approach.
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As you'll see on some of the next slides, we have FDA fast track.
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We have now FDA breakthrough designation as well.
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The first time ever for an opioid product because of the ability to have the ability to turn
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off the activation if somebody has taken too many in an overdose situation.
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We've also been very fortunate to have multiple funding from the NIH, and from the National
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Institute of Drug Abuse in particular and with some of the other institutes and perhaps
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also in the future.
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So let's talk about PF614 itself as the first TAAP opioid product.
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It was granted fast track designation by the FDA in January 2018 because it is different,
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it's built differently through chemistry than abuse deterrent formulations.
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We know now that PF614 is bio equivalent to Oxycontin but with a longer half life.
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That's one of our first goals.
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We have seen that it does support twice a day dosing, BID dosing.
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It resists abuse even when dissolved in water.
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Why?
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Because it's abuse resistance is built into the chemistry, not into a formulation which gives
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us many advantages such as being able to use a liquid formulation for patients who cannot
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swallow capsules or tablets.
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Think about pediatrics, think about geriatrics.

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That makes it something that is certainly easier to administer in a variety of dose forms
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and that is something that we're actively working on.
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We've shown in abuse liability studies that snortng this compound has much less interest
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to recreational drug users than crushed oxycodone.
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We've seen very good safety profile from this compound in six clinical trials that we've
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done to date and we've also verified overdose protection.
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These are all of the objectives that we started out with early in the planning for PF614.
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So what's the next step?
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We are planning to start a study in severe acute
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pain which is a study in patients undergoing abdominal plastic surgery.
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This is a cosmetic surgery for removing excess skin in patients who've lost a lot of weight
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for whatever reasons.
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Usually this is about 80% female, 20% male but it's been developed into a very good model
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of severe postoperative pain and we're going to be able to evaluate different dose levels
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of PF614 to see hopefully that this is something that can be used successfully
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in acute pain.
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The other thing that we're talking about very seriously is doing studies in cancer pain.
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These meet the two different objectives for the use of opioids that Dr. Arrent Nielsen
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had talked about earlier.
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I think that we can do both of these in the next few years and get the product on the market
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ideally for both indications but with specifics in terms of how to ideally use the compound.

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This is PF614 by itself.
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The combination PF614M-PAR is a second generation product.
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It will take a little bit longer to develop but we should have that on the market within
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a year or so after the potential approval of PF614.