The most-promising late-stage pipeline drugs are a varied bunch: cancer therapies employing the immune system, PCSK9 inhibitors targeting cholesterol and biosimilars angling to upset biologies' market share. Some will hit the market with a splash, others will crash and burn due to safety/efficacy issues and the rest could fade into obscurity if competitors win the race to market.

When judging the future of clinical candidates, the only important criterion is whether they will change therapy when approved, notes Bernard Munos, senior fellow at FasterCures. Of a potential drug, Munos asks, “Will patients and physicians clamor for it, as they clamor for [Gilead’s hep.-C pill] Sovaldi or [Merck/Samsung Bioepis’s MK-1293].”

The candidates profiled in this report are based on consultation with a hefty price tag: The year 2015 saw more industry pricing in patients with Duchenne muscular dystrophy. Marin’s agent to generate the muscle protein miss-

CETP inhibitors have been making headlines in the cardiotherapy sector, though not in a good way. Following the lead of Roche and Pfizer, Eli Lilly became the latest company to halt development. Where’s Merck’s astatcepta? Among PCSK9 inhibitors, analysts are waiting to see if Pfizer’s bococizumab can replicate Lipitor’s tardy—but huge—launch. In two pivotal studies Roche’s ocrelizumab showed remarkable improvements over an MS standard of care. The humanized mAb could make a real difference if approved.

And R&D dollars are making their way into the orphan-disease space at a greater clip, including BioMarin’s agent to generate the muscle protein missing in patients with Duchenne muscular dystrophy.

Advancements in diabetes drugs also grabbed our attention, especially Credit Suisse’s forecasts, expected launch dates and success likelihood where available, of featured products.

The JAK inhibitor appears to have similar efficacy and safety to Sanofi’s Aubagio, providing another oral option for needle-adverse patients in need of more effective therapies. But a lack of product differentiation and high prices may go haywire.

Nonetheless, oncologic standouts are the most noteworthy R&D innovation of late. “PD-1/L1 inhibitors are the most remarkable accomplishment in years,” says Richard Evans, founder of SSR Health. “PD-1/L1 inhibitors are the most remarkable accomplishment in years,” says Richard Evans, founder of SSR Health. “PD-1/L1 inhibitors are the most remarkable accomplishment in years,” says Richard Evans, founder of SSR Health. “PD-1/L1 inhibitors are the most remarkable accomplishment in years,” says Richard Evans, founder of SSR Health. “PD-1/L1 inhibitors are the most remarkable accomplishment in years,” says Richard Evans, founder of SSR Health. “PD-1/L1 inhibitors are the most remarkable accomplishment in years,” says Richard Evans, founder of SSR Health. “PD-1/L1 inhibitors are the most remarkable accomplishment in years,” says Richard Evans, founder of SSR Health. “PD-1/L1 inhibitors are the most remarkable accomplishment in years,” says Richard Evans, founder of SSR Health. “PD-1/L1 inhibitors are the most remarkable accomplishment in years,” says Richard Evans, founder of SSR Health.

Perhaps the biggest lingering R&D question involves late-stage biosimilars like Merck/Samsung Bioepis’s MK-1293. The safety profile was comparable to approved oral agents Tecfidera, Gilenya and Ocrevus (Ph.III).

In phase III RA-BEAM). The agent also proved superior to adalimumab on secondary endpoints of clinical efficacy—ACR20 assessment at week 24. The trial also met its key secondary endpoints, including ACR50, ACR70 and DAS 28-CRP. The safety profile was comparable to adalimumab.

Thought Comment: There are at least 20 biosimilar adalimumab, etanercept and infliximab agents in global development, but the real question is how this will play out in major markets. We expect the market to support no more than four biosimilar versions of a given drug and believe that deals with payers will dictate winners and losers.

What the physicians are saying: Despite concerns that these complex biosimilars aren’t a perfect replacement, biosimilars will undoubtedly play a leading role in future RA treatment. Most physicians recognize that biosimilars lower costs and give access to a greater number of patients in need of more effective therapies. But a lack of product information and experience will impair their trust. Physician education is one of numerous hurdles the biosimilar will face upon launch as multiple other assets in late phase look to capture a piece of the Humira pie. —Anita Agier, head of Disease Atlas, GfK Healthcare.

The pipeline report 2016

BIG-TIME UPSIDE

A peek at 159 aspiring agents, with profiles on 17 that could shoot to stardom.

The Pipeline Report 2016

Rebecca Mayer Knutsen has the forecast

THERAPEUTIC CATEGORIES

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Respiratory p. 37
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Ozanimod Celgene
Indication: Relapsing MS/ulcerative colitis (Ph.III)
What the clinical trials found: Ozanimod in RMS reduced MRI brain lesion activity and met key secondary MRI-based endpoints (RADIANCE, Ph.II). Ozanimod in UC met all efficacy endpoints with statistical significance in patients on the 1mg dose after 32 weeks of treatment (TOUCHSTONE, Ph.II). No severe AEs observed to date.
Credit Suisse Success Probability and Credit Suisse revenue forecasts: $900 million in annual global sales by 2020
What the physicians are saying: Trial findings show ozanimod’s ability to reduce MS relapses and brain lesions. Early opinions indicate a similar safety profile to approved oral agents Tecfidera, Gilenya and Sanofi’s Aubagio, providing another oral option for needle-adverse patients. If results from ongoing Phase III studies show superiority to Biogen’s Avenex and similar or better safety to the current oral therapies, then neurologists could add a formidable weapon to the MS arsenal. —Paul Wojciak, research director, GfK

OTHER KEY PRODUCTS IN THE PIPELINE

The pipeline report 2016

Big-Time Upside

Other key products in the pipeline

Baricitinib Eli Lilly/Incyte
Indication: RA (Ph.III)
What the clinical trials found: The daily oral demonstrated superiority compared to placebo after 12 weeks based on ACR20 response (Ph.III). RA-BEAM). The agent also proved superior to adalimumab on key secondary endpoints of ACR20 response and improvement in DAS28-40CRP score. A few occasional AEs were reported.
Credit Suisse Success Probability and Credit Suisse revenue forecasts: $1.09 billion in global annual sales by 2020
What the physicians are saying: Baricitinib is the most advanced competitor to first-in-class Xeljanz, which caters to patients who have failed anti-TNFs and/or methotrexate; an area where physicians have been awaiting more options. However, price could be a barrier to baricitinib uptake. With the biologic market’s expected growth by 2020, JAK inhibitors have room to develop in a market that seeks effective therapies to improve patient quality of life. —Anita Agier, head of Disease Atlas, GfK Healthcare.

ABP 501 (adalimumab biosimilar) Amgen
Indication: RA (Ph.III)
What the clinical trials found: A Phase III trial in patients with moderate-tosevere RA met its primary endpoint of clinical equivalence between the adalimumab biosimilar and branded adalimumab groups, as measured by ACR20 assessment at week 24. The trial also met its key secondary endpoints, including ACR50, ACR70 and DAS 28-CRP. The safety profile was comparable to adalimumab.
Thought Comment: There are at least 20 biosimilar adalimumab, etanercept and infliximab agents in global development, but the real question is how this will play out in major markets. We expect the market to support no more than four biosimilar versions of a given drug and believe that deals with payers will dictate winners and losers. What the physicians are saying: Despite concerns that these complex biosimilars aren’t a perfect replacement, biosimilars will undoubtedly play a leading role in future RA treatment. Most physicians recognize that biosimilars lower costs and give access to a greater number of patients in need of more effective therapies. But a lack of product information and experience will impair their trust. Physician education is one of numerous hurdles the biosimilar will face upon launch as multiple other assets in late phase look to capture a piece of the Humira pie. —Anita Agier, head of Disease Atlas, GfK Healthcare.

Gilead Science
Indication: Hepatitis C
What the clinical trials found: Sovaldi met its key secondary endpoints, including ACR50, ACR70 and DAS 28-CRP. The safety profile was comparable to adalimumab.
Thought Comment: There are at least 20 biosimilar adalimumab, etanercept and infliximab agents in global development, but the real question is how this will play out in major markets. We expect the market to support no more than four biosimilar versions of a given drug and believe that deals with payers will dictate winners and losers. What the physicians are saying: Despite concerns that these complex biosimilars aren’t a perfect replacement, biosimilars will undoubtedly play a leading role in future RA treatment. Most physicians recognize that biosimilars lower costs and give access to a greater number of patients in need of more effective therapies. But a lack of product information and experience will impair their trust. Physician education is one of numerous hurdles the biosimilar will face upon launch as multiple other assets in late phase look to capture a piece of the Humira pie. —Anita Agier, head of Disease Atlas, GfK Healthcare.
BIG-TIME UPSIDE

CARDIOLOGY

PRODUCTS GENERATING BUZZ

Bococizumab (RN316) Pfizer

Indication: CV disorders/hypercholesterolemia/hyperlipidemia (Ph.III)

What the clinical trials found: Patients with hyperlipidemia who were on concurrent statin therapy saw significantly reduced LDL-C at week 12 compared with placebo in a Phase II study. The greatest reductions were observed in patients treated with dose regimens of 150mg twice weekly (-52.4mg/dL) or 300mg once weekly (-44.9mg/dL). AEs were similar across placebo and treatment groups.

Credit Suisse Revenue Forecast: $117 million in annual global sales by 2020

What the analysts are saying: Bococizumab will have to fight a battle with established products that have provided real-world experience to physicians. Some believe that bococizumab may be able to achieve “best in class” status within the PCSK9 class through its technological partnership with Halseyme. The company’s delivery platform promises to improve the efficacy of individual subcutaneous injections and could reduce the required dose, giving bococizumab an edge over alirocumab and evolocumab, which are also administered subcutaneously, in the judgment that once ruled the cholesterol management arena with Lipitor, has experience with entering disease areas late. Coupled with a legacy in cardiology, bococizumab shouldn’t be count-out. — Alex Buatian, VP GfK Health

Anacetrapib Merck

Indication: Heterocyclic hypercholesterolemia/hyperliproteinemia (Ph.III)

What the clinical trials found: Anacetrapib decreased LDL-C (from 81 to 45 vs 82 to 77mg/dL for placebo; p < 0.001) and increased HDL-C (from 40 to 41 vs 40 to 46mg/dL for placebo; p < 0.001) at 24 weeks in patients with CHD or CHD risk-equivalent disease (DEFINE-Ph.III) with a good cardiac safety profile.

Credit Suisse Success Probability: 52%. Expected launch: 2018 (Source: Credit Suisse)

Credit Suisse Revenue Forecast: $374 M in annual global sales by 2020

What the analysts are saying: Bococizumab will have to fight a battle with established products that have provided real-world experience to physicians. Some believe that bococizumab may be able to achieve “best in class” status within the PCSK9 class through its technological partnership with Halseyme. The company’s delivery platform promises to improve the efficacy of individual subcutaneous injections and could reduce the required dose, giving bococizumab an edge over alirocumab and evolocumab, which are also administered subcutaneously, in the judgment that once ruled the cholesterol management arena with Lipitor, has experience with entering disease areas late. Coupled with a legacy in cardiology, bococizumab shouldn’t be count-out. — Alex Buatian, VP GfK Health

Firazurin AstraZeneca

Indication: Congestive heart failure/diabetic nephropathies (Ph.III)

What the clinical trials found: Firazurin was equivalent to eplerenone in reducing a marker of heart failure (NT-ProBNP) and at the optimal dose of 10mg/20mg, there was a 4% reduction in cardiovascular events and mortality. The agent also exhibited signs of a better side-effect profile in the Phase IIb ARTS-HF Credit Suisse Success Probability: 25%. Expected launch: 2020 (Source: Credit Suisse)

Credit Suisse Revenue Forecast: $171 million in annual global sales by 2020

What the physicians are saying: Many doctors are discouraged from using MRAs, including eplerenone and spironolactone, because of the need for monitoring, and it’s estimated that only a third of patients who could benefit from these agents actually receive them. Feracria Filippatos, MD from Athens University Hospital Attikon, Greece, said Firazurin has greater selectivity for the mineralocorticoid receptor than spironolactone and greater affinity for the receptor than eplerenone. He noted the agent distributes equally to the heart and the kidney, in contrast to eplerenone, which has been shown to distribute primarily to the kidney. In theory, Firazurin should demonstrate potency and safety advantages. — Alex Buatian, VP GfK Health

FINERONE BAYER

Indication: Type 2 diabetes (Ph.III)

What the clinical trials found: The Phase III SUSTAIN-7 trial showed that once-weekly injection of 1mg semaglutide provided better glycemic control and greater weight loss than 2mg AstraZeneca’s Byetta once-weekly. Semaglutide was generally safe and well tolerated.

Credit Suisse Success Probability: 45%. Expected launch: 2017 (Source: Credit Suisse)

Credit Suisse Revenue Forecast: $975 million in annual global sales by 2020

What the physicians are saying: Despite new therapy advancements, insulin patients continue to struggle with control. Our data over the past few years have shown a increase in GLP-1 use in combination with insulin, albeit at low levels. Given Lantus’s strong standing in the market and the benefits attributable to GLP-1’s, physicians will appreciate the convenience of the liraniptenate and Lantus combination. Notably, the addition of a GLP-1 to basal insulin offers the possibility of potential insulin control without the risk of weight gain associated with adding a prandial insulin. And, it simplifies the regimen for patients who are already treating several other conditions in addition to diabetes. — Mary McBride, VP GfK Roper Diabetes

Semaglutide Novo Nordisk

Indication: Type 2 diabetes (Ph.III)

What the clinical trials found: The Phase III SUSTAIN-7 trial showed that once-weekly injection of 1mg semaglutide provided better glycemic control and greater weight loss than 2mg AstraZeneca’s Byetta once-weekly. Semaglutide was generally safe and well tolerated.

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OTHER KEY PRODUCTS IN THE PIPELINE

PRODUCTS GENERATING BUZZ

LixiLan (lixisenatide/insulin glargine) Sanofi

Indication: Type 2 diabetes (Ph.III)

What the clinical trials found: In a Phase-III trial vs Sanofi’s Lantus, lixisenatide/insulin glargine combination met the primary endpoint of statistically superior reduction in HbA1c (LixiLan-L). The Phase III LixiLan-D trial found the fixed-ratio, once-daily injection of lixisenatide/insulin glargine combination superior to both Lantus (insulin glargine) and Sanofi’s LixiLan (lixisenatide) alone in reducing HbA1c. The combination was well-tolerated with few reported AEs. Credit Suisse Success Probability: 50%. Expected launch: 2017 (Source: Credit Suisse)

Credit Suisse Revenue Forecast: $975 million in annual global sales by 2020

What the physicians are saying: Despite new therapy advancements, insulin patients continue to struggle with control. Our data over the past few years have shown a increase in GLP-1 use in combination with insulin, albeit at low levels. Given Lantus’s strong standing in the market and the benefits attributable to GLP-1’s, physicians will appreciate the convenience of the liraniptenate and Lantus combination. Notably, the addition of a GLP-1 to basal insulin offers the possibility of potential insulin control without the risk of weight gain associated with adding a prandial insulin. And, it simplifies the regimen for patients who are already treating several other conditions in addition to diabetes. — Mary McBride, VP GfK Roper Diabetes

OTHER KEY PRODUCTS IN THE PIPELINE

PRODUCTS GENERATING BUZZ

Ertugliflozin Pfizer/Merck

Indication: Type 2 diabetes (Ph.III)

What the physicians are saying: Merck and Samsung Bioepis’ MK-1293 is one of several insulin glargine biosimilars looking to take share from Lantus. While physicians appreciate the cost savings and expanded insulin options biosimilars will provide, the speed with which physicians are ready to move patients to MK-1293 remains to be seen. Uptake will require strong supporting data and a comfort level that transitioning to a biosimilar will be in the patient’s interest. We await and see attitude will prevail among those requiring reassurance that the differences between MK-1293 and Lantus are not clinically meaningful. Uptake will also be linked to MK-1293’s ability to obtain interchangeability status with Lantus at the pharmacy. — Mary McBride, VP GfK Roper Diabetes

MK-1293 (insulin glargine biosimilar) Merck/Samsung Bioepis

Indication: Type 1/2 diabetes (Ph.III)

What the clinical trials found: In a Phase III study vs Sanofi’s Lantus, the mean change in hemoglobin A1c (A1C) from baseline over 24 weeks is non-inferior in Type 1 diabetes patients treated with MK-1293 (insulin glargine biosimilar). No major safety issues seen in/To/Think Comment: Biosimilar insulin will be an easier sell to doctors than biosimilars for rheumatoid arthritis or cancer. We expect this to be taken up fairly efficiently, and more importantly, for biosimilar insulins to become cornerstones of diabetes franchises.

What the physicians are saying: Merck and Samsung Bioepis’ MK-1293 is one of several insulin glargine biosimilars looking to take share from Lantus. While physicians appreciate the cost savings and expanded insulin options biosimilars will provide, the speed with which physicians are ready to move patients to MK-1293 remains to be seen. Uptake will require strong supporting data and a comfort level that transitioning to a biosimilar will be in the patient’s interest. We await and see attitude will prevail among those requiring reassurance that the differences between MK-1293 and Lantus are not clinically meaningful. Uptake will also be linked to MK-1293’s ability to obtain interchangeability status with Lantus at the pharmacy. — Mary McBride, VP GfK Roper Diabetes

OTHER KEY PRODUCTS IN THE PIPELINE
Abemaciclib

**Roche**

**Indication:** Breast cancer (Ph.III)

**What the clinical trials found:** A Phase I trial of abemaciclib found a 49% disease control rate for the 57 evaluable patients with NSCLC, including 2 partial responses and 26 patients with stable disease. The disease control rate for the KRAS-mutant patients was 55% vs. 38% for the KRAS wild-type patients. Leukopenia and neutropenia were consistent with previous studies.

**Credit Suisse Success Probability:** 75%. Expected launch: 2019

**Credit Suisse forecast:** $4.45 billion in global sales by 2020

**What the analysts are saying:** Benzalumab is part of a new era of treatments for severe asthma that will provide benefits we haven’t had for uncontrolled patients. With few options other than medium- to high-dose inhaled corticosteroids and LABAs, patients suffer from both the emotional and physical burden of extended symptomatic states and multiple hospital visits due to exacerbations. Additional effective therapies are a high-demand unmet need in this market. Primary concerns remain around potential safety concerns and identifying patients who will benefit from treatments. Still, most physicians see the clinical value these new entrants offer and are optimistic about future patient outcomes.

— Anita Agier, head of Disease Atlas, GfK Healthcare

**PRODUCTS GENERATING BUZZ**

**BIG-TIME UPSIDE**

**ONCOLOGY**

**PRODUCTS GENERATING BUZZ**

**RESPIRATORY**

**OTHER KEY PRODUCTS IN THE PIPELINE**

**PRODUCTS GENERATING BUZZ**

**RESPIRATORY**

**OTHER KEY PRODUCTS IN THE PIPELINE**
OTHER

PRODUCTS GENERATING BUZZ

NEUROLOGY
Ocrelizumab Roche
Indication: Multiple sclerosis (Ph.III)
What the clinical trials found: OPERA I and OPERA II studies (Ph. III) met primary endpoint with a nearly 50% reduction in annualized relapse rate over a two-year period. Overall, AEs were similar to interferon beta-1a in both studies; the most common AEs were mild to moderate infusion-related reactions.
Credit Suisse Success Probability and inThought Comment: 60%. After 15 years in development with failures in RA and lupus, this Rituxan follow-on compound appears to be a game changer in MS. In addition to being the first drug that really works in primary progressive MS, it’s on track to be a serious threat to all the current relapsing remitting MS drugs. Expected launch: 2017 (Source: Credit Suisse)
Credit Suisse revenue forecast: $2.23 billion in global annual sales by 2020
What the physicians are saying: Based on positive Phase II and Phase III trial results, some neurologists feel that ocrelizumab’s efficacy profile could eventually top that of Tysabri (natalizumab). What may separate ocrelizumab from other effective marketed brands is its promising positive data in primary progressive MS, a form of the disease currently with no approved treatments. While trial results also show great promise in the much more prevalent form of MS, relapsing-remitting MS, the product’s benefit/risk profile may deter neurologists from calling on the agent too early and reserve it only for more progressive cases of the disease. Even if this is the case, it would be neurologists’ first approved therapy for these patients.
—Paul Wojciak, research director, GfK

ORPHAN
Kyndrina (drisapersen) BioMarin
Indication: Duchenne muscular dystrophy (Pre-reg.)
What the clinical trials found: A Phase III study (DEMAND III) showed a 49m difference in the six-minute walk test (6MWT) between those on continual active treatment (n = 52) and those who had been on placebo for the first 48 weeks followed by active treatment (n = 31). AEs were consistent with previous trials.
Jefferies revenue forecast: $1.06 billion in global sales by 2021
Credit Suisse Success Probability and Jefferies comment: 50%. Despite imperfect data, our due diligence indicates a likely positive outcome (we assume ~75% probability for success). Expected launch: 2016 (Sources: Credit Suisse; Jefferies)
What the physicians are saying: There are few treatment options for patients and families affected by Duchenne muscular dystrophy (DMD). The FDA has granted BioMarin’s drisapersen priority review status and approval is expected in 2016. [Its PDUFA date is scheduled for 12/27/15. —Ed.] Drisapersen targets exon 51 by “skipping” this genetic code and thereby allowing the creation of partially functional dystrophin, the muscle protein missing in DMD. It is estimated that 13% of DMD’s population will benefit from this treatment. It’s not a cure, but physicians are expected to welcome this drug into their limited armamentarium as well as Sarepta Therapeutic’s eteplirsen, which has a similar mechanism of action. —Joanne French, VP, new products, GfK

OTHER KEY PRODUCTS IN THE PIPELINE

INFECTIONOUS DISEASE
Asunaprevir+beclabuvir+daclatasvir BMS Hepatitis C (Ph.III)
Fostemsavir BMS HIV-1 inf. (Ph.III)
PRO 140 CytoDyn HIV/AIDS (Ph. III)
Emtricitabine+tenofovir alafenamide Gilead TJ/2 diabetes (Ph.III)
Insulin glargine biosimilar Eli Lilly HIV-1 inf. (Ph.III)
Tenofovir alafenamide Gilead Hepatitis B (Ph.III)
GSK 143713A GlaxoSmithKline Herpes (Ph.III)
Tafenoquine GlaxoSmithKline Malaria (Ph.III)
Dolutegravir+rilpivirine Janssen/ ViIV Healthcare HIV/AIDS (Ph.III)
Actoxumab + bezlotoxumab Merck Clot, diff. inf. (Ph.III)
Doravirine+tamivudine+tenofovir disoproxil fumarate Merck HIV-1 inf. (Ph.III)
Elbasvir+grazoprevir Merck Hepatitis C (Pre-reg.)
rVSV 5 GP/VP40 Merck/NewLink Genetics Ebola (Ph.III)
PRSI Merck/Sanoﬁ DTP-HebB- Polo-Hb (Pre-reg.)
V 212 Merck Herpes zoster (Ph.III)
Amoxicillin+omeprazole+rifabutin RedHill BioPharma Helicobacter inf. (Ph.III)
Ertapenem Tetraphase cUTI/cIAI (Ph.III)
ORPHAN
Firdapse Catalyst LEMS (Pre-reg.), CMS (Ph.III)
AG-221 Celgene AMI (Ph.III)
Farletuzumab Eisai/Ludwig Institute for Cancer Research Ovarian cancer (Ph.III)
ISIS TTRtx GSK/ISIS Amyloid polyneuropathy (Ph.III)
AG-221 Infinity CLL (Ph.III)
Obeticholic acid Intercept Primary biliary cirrhosis (Pre-reg.)
NEUROLOGY
Esketamine Acorda Therapeutics Parkinson’s (Ph.III)
Buprenorphine/samidorphan Alkermes MDD (Ph.III)
Aducanumab Biogen Alzheimer’s (Ph.III)
Brivaracetam UCB Epilepsy (Pre-reg.)
Tanezumab Eli Lilly Pain (Ph.III)
LY 2951742 Eli Lilly Migraine (Ph. III)
Esketamine J&J MDD (Ph.III)
Idalopidine Lundbeck Alzheimer’s (Ph.III)
Gantenerumab Roche Alzheimer’s (Ph.III)
Mirogabalin Daiichi Sankyo Fibromyalgia pain (Ph.III)
Oxycodeone/naltrexone Pfizer Pain (Pre-reg.)
Pregabalin controlled-release Pfizer Fibromyalgia/postherpetic neuralgia (Ph.III)
WOMEN’S HEALTH
Elagolix AbbVie Endometriosis (Ph.III)
Follitropin alfa biosimilar Allergan/Itero Female infertility (Ph.III)
Bay98-7196 Bayer HealthCare Contraception (Ph.III)
Prasterone vaginal Bayer HealthCare/Endoconitcs Vaginal atrophy (Ph.III)
Amphora Evofem Contraception (Pre-reg.)
MK 8342B Merck Contraception (Ph.III)