

Only a couple of **beats away** from **regulatory approval**, the novel dual-action **Vanlev** could prove to be the **next blockbuster** for treating **hypertension**

**IN A SECOND GO-ROUND** for a drug that once was predicted to become a high flier, Bristol-Myers Squibb is one FDA approval away from launching the next best medication for the treatment of hypertension, a condition that affects about 50 million Americans. Nearly two years ago, Bristol-Myers Squibb was set to seek approval for Vanlev, but withdrew the NDA because of a potentially life-threatening side effect. Analysts, who had once predicted blockbuster status for Vanlev, now are cautiously optimistic about the drug's chances and market potential based on newly conducted studies.

Upon approval, the novel vasopeptidase inhibitor Vanlev (omapatrilat) will enter an antihypertensive market, which is expected to reach \$38.5 billion by 2003, according to a study by Front Line Strategic Consulting Inc. Vanlev is expected to take market share away from Merck, Pfizer, and Novartis, with sales close to \$2.5 billion by 2006.

In mid-December 2001, Bristol-Myers Squibb resubmitted a new drug application (NDA) with the U.S. Food and Drug Administration for Vanlev for the treatment of hypertension.

The NDA included data from the 25,000-patient OCTAVE (Omapatrilat Cardiovascular Treatment Assessment Versus Enalapril) trial

comparing Vanlev to enalapril, a member of the widely used class of antihypertensive drugs known as ACE inhibitors. Enalapril is the chemical name for Vasotec, which is marketed by Merck & Co.

Vanlev will be the first in a class of drugs called vasopeptidase inhibitors, which will compete against established classes of blood-pressure drugs, including angiotensin converting enzyme (ACE) inhibitors, beta blockers, calcium channel blockers, thiazide diuretics, and angiotensin receptor blockers.

Like ACE inhibitors, vasopeptidase inhibitors block angiotensin converting enzymes, which raise blood pressure, while stopping another enzyme called neutral endopeptidase. Through this dual action, Vanlev protects the body's supply of other helpful substances that make blood vessels relax and prevent dangerous overgrowth of heart muscle.

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### Let the duel begin

Vanlev's dual action and superiority in clinical trials against AstraZeneca's Zestril, a once-daily, long-acting ACE inhibitor, and Pfizer's Norvasc, a long-acting calcium channel blocker, are expected to set

**V**asopeptidase inhibitors (VPIs) have a novel mechanism of action, which shows greater blood-pressure reduction than other classes of antihypertensive therapeutics in clinical studies. Other novel mechanisms expected to impact the market include selective aldosterone antagonists (SAAs) and renin inhibitors (RIs). These classes also promise improved safety and/or efficacy profiles.

Bristol-Myers Squibb has the clear lead in the VPI class, with Vanlev awaiting U.S. regulatory approval, as well as a second generation VPI compound, 189921, in clinical development. However, several other companies are expected to bring their novel drugs to market in the next few years.

In February 2002, Pharmacia submitted its NDA for eplerenone for the treatment of hypertension. Eplerenone is a SAB being developed for once-daily oral therapy designed specifically to block the effects of the hormone aldosterone. Aldosterone is a key component within the RAAS (renin angiotensin aldosterone system) and plays a significant role in the body's regulation of the cardiovascular system.

Novartis' oral renin inhibitor, SP100, would be the first in a new class of hypertensive treatments. Renin, unlike angiotensin converting enzyme inhibitors, is completely specific for angiotensinogen, and renin inhibitors are expected to be virtually free of side effects. Speedel Pharma in Basel, Switzerland, in-licensed development rights from Novartis. Speedel was expected to complete Phase IIb trials last fall, at which point Novartis' plans were to exercise its option to recover rights and proceed to Phase III trials.

Aventis Pharma's vasopeptidase inhibitor 100240 is a potential monotherapy for hypertension and congestive heart failure. The compound's dual mode of action blocks the angiotensin converting enzyme and the neutral endopeptidase. The compound is entering Phase IIb clinical trials based on its effect of lowering blood pressure.

Bristol-Myers Squibb's 189921 is in Phase II clinical trials for the treatment of hypertension and Phase I clinical trials for treating congestive heart failure. Analysts expect the second-generation VPI will be ready for launch in 2005.

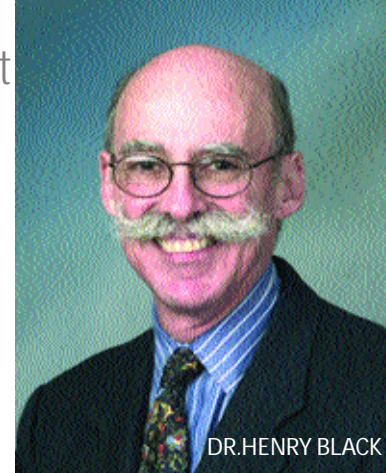
"Aventis' and BMS's new compounds are the most likely competition to Vanlev but it's too early to really predict the outcome," says Tracy Yeo, Ph.D., associate and co-author of Front Line Strategic Consulting Inc.'s anti-hypertensive therapeutics report. "We don't expect the other compounds to be significant competition for Vanlev, because Vanlev will already have secured a lead position."

Dr. Yeo says Novartis' renin inhibitor and Pharmacia's eplerenone also could impact the market: "We are projecting sales of each drug to be about \$585 million by 2006, but we don't think either one will be any competition for Vanlev."



DR. NANCY ZHANG  
AND DR. TRACY YEO

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DR. HENRY BLACK

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it apart from these approved hypertensive treatments.

In clinical trials, Vanlev was reported to significantly lower both systolic and diastolic pressure. "From what we know so far, Vanlev seems to be the single best agent for systolic blood-pressure reduction," says Dr. Henry Black, associate dean for research and the chairman of the department of preventive medicine at Rush Presbyterian-St. Luke's Medical Center. Dr. Black is a board-certified nephrologist with three decades of experience in preventive cardiology. He is an internationally known expert on hypertension, with special interests in the evaluation of antihypertensive medications, the study of secondary causes of hypertension, and hypertension in the elderly. Dr. Black serves on the executive committee of the American Heart Association Council on High Blood Pressure Research.

Dr. Black, who has been involved with the clinical trials for the new compound, says this drug shines because the reduction of systolic blood pressure is the biggest unmet need, "Vanlev also seems to be a more powerful agent in that it works a bit better than what we currently have for controlling diastolic pressure."



DR. NICOLA MAIDWELL

Vanlev represents a truly unique entrant to the field, a new therapeutic class, and in our most optimistic scenario could generate sales equal to 8% of market share by 2010.

Systolic pressure is the pressure in the arteries when the heart beats. Diastolic pressure is the pressure between beats. Ideal blood pressure is less than 140 over 90; systolic is the first and larger of the two numbers.

According to Dr. Michael Weber, professor of medicine and associate dean for research at SUNY Downstate College of Medicine, systolic blood pressure is more important than diastolic pressure to be controlled because systolic pressure is what is closely linked to the risk of major cardiovascular events and stroke.

"This is interesting news for the medical community," Dr. Weber says. "Vanlev is the most powerful oral drug that has ever been available. Currently 30% to 40% of patients requiring blood pressure control have their needs met by a single drug. Adding a second drug takes care of 75% to 80% of patients. Clinical studies suggest Vanlev has the advantage of starting patients off at a higher level — with about 50% of these patients under control with one drug. If another drug is added, this means controlling blood pressure in about 90% of patients."

### Pressure points

Even as Vanlev has clinical advantages in controlling blood pressure, the compound has been linked to adverse events. Events that were severe enough for Bristol-Myers Squibb

## Bristol-Myers Squibb — Getting Back on Track

Vanlev is expected to be the next significant drug to be launched from Bristol-Myers Squibb's pipeline, but certainly not the last. Over the next 12 months, Bristol-Myers Squibb Co. plans to submit an unprecedented number of regulatory submissions, including global regulatory filings for five new potential blockbuster compounds. The company has moved aggressively over the past year to position itself to reach this goal, redesigning itself from a diversified health and personal-care business to a medicines-focused business. Bristol-Myers Squibb has eliminated — through reductions and attrition — about 4,000 positions, including positions at DuPont Pharmaceuticals, which was acquired in October 2001 for \$7.8 billion. The acquisition, which was announced June 7, is a key element of the company's growth strategy.

"The acquisition of DuPont Pharma ... enables us to play a greater leadership role, particularly in the areas of virology and cardiovascular diseases, where there is a pressing need to expand treatments and find new and better therapies," says Peter R. Dolan, 46, chairman and CEO of Bristol-Myers Squibb.

With this acquisition, Bristol-Myers Squibb gains several important in-line products, including Sustiva (efavirenz), the leading non-nucleoside reverse transcriptase inhibitor for the treatment of HIV/AIDS; Coumadin (warfarin sodium tablets, USP), a widely used oral blood anticoagulant; and Cardiolite (Kit for the preparation of Technetium Tc99m Sestamibi for Injection), a leading cardiovascular medical imaging agent. The company also gains a R&D pipeline that contains a number of early compounds with novel mechanisms that have the potential to be first in class and blockbusters. The pipeline includes compounds in five therapeutic areas — virology, cardiovascular disease, inflammatory disease, cancer, and disorders of the central nervous system.

In keeping with its medicine-focused strategy, Bristol-Myers Squibb sold its Clairol hair care business, spun off its Zimmer orthopedic implants business, and announced an agreement to invest in ImClone Systems to co-develop and co-promote Erbitux, ImClone's investigational cancer therapy. In February 2002, the company proposed steps to fundamentally restructure its relationship with ImClone. "If these conditions are accepted, Bristol-Myers Squibb will take the lead in the FDA approval process and other clinical and regulatory matters related to Erbitux," Mr. Dolan says.

At a recent company presentation of its research pipeline to the investment community, Bristol-Myers Squibb executives shared new details about some of the more than 50 compounds in the company's early-stage and late-stage pipeline and provided highlights of a selection of its more than 100 drug-discovery programs.

"Our Strategy for Growth plan, which was announced just one year ago, has already delivered significant results," Mr. Dolan says. "As a result of these efforts, we believe we have the products that will allow us to achieve our goal of launching three potential blockbuster products a year for several years starting in 2003 and we are hopeful that the first of these products may launch in 2002."

Heading up the company's aggressive R&D initiatives is Dr. Elliott Sigal, who in January 2002 was named to a new position — senior VP, global clinical and pharmaceutical development. In this role, Dr. Sigal is responsible for overseeing the company's global clinical organization, including the clinical research operations and product development teams across all therapeutic areas. Additionally, Dr. Sigal has oversight of pharmaceutical development and project management. Dr. Sigal joined Bristol-Myers Squibb in 1997 as VP, applied genomics, where he developed and implemented the company's strategy for applying advanced genomics techniques to the company's R&D pipeline. Before his recent appointment, Dr. Sigal was senior VP, drug discovery and exploratory development.

"Elliott's broad depth of experience has played a key role in the strengthening of our dis-

covery efforts, creating an early pipeline that has grown in size and innovation," Mr. Dolan says. "I am confident that under his leadership, the newly combined clinical and pharmaceutical development organization will succeed in advancing the record number of innovative blockbuster brands they are poised to deliver into the marketplace, among them Vanlev for hypertension and heart failure, aripiprazole for schizophrenia and related disorders, and atazanavir for HIV/AIDS."

Within the next 12 months, Bristol-Myers Squibb expects to submit global regulatory filings for the following potential best-in-class or first-in-class products:

■ **Aripiprazole** — is a novel and potentially best-in-class compound under investigation for the treatment of schizophrenia and related disorders. Aripiprazole is a next-generation antipsychotic that, in completed trials, has demonstrated efficacy with an excellent safety and tolerability profile and once-daily dosing with no need for titration in Phase III clinical studies. Bristol-Myers Squibb announced that in conjunction with Otsuka Pharmaceutical Company Ltd., it submitted the NDA for aripiprazole Oct. 31, 2001. The company also submitted for filing the Marketing Authorisation Application (MAA) in Europe in December 2001.

■ **Atazanavir** — has the potential to become the best-in-class protease inhibitor. The compound would be the only protease inhibitor to be taken orally once a day. In completed studies, atazanavir has a favorable HIV resistance and lipid profile and, unlike other protease inhibitors, has not been associated with elevated lipid levels. With the addition of atazanavir, Bristol-Myers Squibb's virology portfolio would have once-a-day therapies in each antiretroviral class. The company plans to complete the global regulatory submissions for atazanavir by the second half of 2002.

■ **Desquinolone** — Des-6-fluoroquinolone is a novel quinolone antibiotic that, based on completed studies, has demonstrated excellent safety and resistance profiles. The company plans to complete the des-6-fluoroquinolone global regulatory submissions for multiple indications in the second half of 2002.

■ **Erbix (cetuximab)** — formerly known as IMC-C225, is a first-in-class monoclonal antibody that is being co-developed with ImClone Systems Inc. In clinical studies, the compound has demonstrated activity in patients with refractory tumors who have failed to respond to other treatment options and is being developed for initial use in treating advanced colorectal cancer. Bristol-Myers Squibb and ImClone Systems also are exploring the potential of Erbix in treating other tumor types, including refractory head and neck tumors and pancreatic cancer. ImClone Systems completed the submission of the Biologics License Application (BLA) for Erbix, for the treatment of advanced colon cancer that is refractory to irinotecan. ImClone Systems announced on Dec. 28, 2001, that the FDA

advised that at this time it is not accepting for filing the company's rolling BLA for Erbix in its current form. Neither the acceptance nor non-acceptance of the BLA filing is a determination of the approvability of Erbix.

■ **Vanlev (omapatrilat)** — is a novel NEP/ACE inhibitor for the treatment of hypertension. Vanlev also is being developed as a treatment for congestive heart failure. The company re-submitted the filing of the Vanlev NDA for hypertension in December 2001.

**B**ristol-Myers Squibb has tripled the number of compounds that are in full-stage or late-stage development. In addition to the five products that are planned for global submissions within the next 12 months, the company's goal is to have nine additional drug candidates in full development by the end of 2002. Importantly, seven of these compounds were discovered in-house at Bristol-Myers

Squibb and two were discovered at DuPont Pharmaceuticals.

The nine additional compounds that are expected to be in full development in 2002 include:

■ **CTLA4-Ig** — is a biologic compound with a novel mechanism of action that has shown promise in the treatment of rheumatoid arthritis. The potential of CTLA4-Ig also is being explored for the treatment of multiple sclerosis.

■ **Dual PPAR agonist** — is for the treatment of type 2 diabetes and other metabolic disorders, and appears to have the potential to simultaneously lower triglycerides, increase insulin sensitivity, and decrease glucose levels.

■ **Entecavir** — is a nucleoside analog for treating hepatitis B.

■ **Epothilone** — is a novel epothilone compound, with potential activity against taxane resistant tumors, and is being developed as a possible first-line cancer treatment.

■ **Factor Xa inhibitor** — is an oral compound that inhibits clot formation in development for the treatment of deep-vein thrombosis.

■ **Farnesyltransferase inhibitor** — is a unique compound for cancer that appears to trigger a very unusual and potent cell-killing pathway in cancer cells as a way of inhibiting the ras oncogene.

■ **LEA 29y** — is a fusion protein, similar in mechanism to CTLA4-Ig, which has the potential to prevent organ transplant rejection.

■ **Next Generation NNRTI** — is a next-generation non-nucleoside reverse transcriptase inhibitor that has the potential to provide an additional antiretroviral option for patients with HIV/AIDS.

■ **Superstatin** — is a next generation, structurally novel member of the statin class that has demonstrated impressive potency in lowering lipids.



Elliott Sigal's broad depth of experience has played a key role in strengthening BMS's discovery efforts, creating an early pipeline that has grown in size and innovation.



DR. MICHAEL WEBER

This is interesting news for the medical community. Vanlev is the most powerful oral drug that we have ever had available. Most patients need two drugs to get their blood pressure under control.

to withdraw its original NDA in April 2000, just months after its submission.

The original NDA was withdrawn pending evaluation of data in response to FDA questions concerning angioedema, an infrequent side effect that causes swelling around the face and throat.

Despite the company's claims that only just more than 1% of patients showed angioedema, and even though angioedema is a well-known side effect observed with another class of anti-hypertensive drugs, the FDA asked Bristol-Myers Squibb to withdraw the NDA for Vanlev. The FDA was particularly worried about four cases where patients actually needed intubation to clear their airways.

Analysts anticipate that Bristol-Myers Squibb's most recent clinical trials demonstrate that the adverse reaction of angioedema is controlled. However, without having seen the clinical results, there is still some uncertainty as to what the final FDA labeling will be for the compound.

"The jury is still out on Vanlev's actual impact," says Joseph Zammit-Lucia, president of Cambridge Pharma Consultancy. "Expectations are big, but nobody has seen the results of the latest studies."

"The absolute worst-case scenario is that the FDA will throw omapatrilat out and not approve it," says Herman Saftlas, an equity analyst with the S&P Equity Group. "But that's not likely. BMS refiled so the company must have the data to support a launch. The real question for the drug, and its impact on the market, is what the label will be and how broad a usage the FDA will give Vanlev."

Vanlev was expected to be one of the blockbuster launches of 2000. Market reaction to the news that Bristol-Myers Squibb had withdrawn its NDA for Vanlev was swift and devastating. According to one analyst, the price of Bristol-Myers Squibb common stock plunged 29% in a single trading day, falling more than \$18.13 a share, to \$47.00 a share from \$62.13 a share on extremely heavy trading volume. In

addition, the Vanlev NDA withdrawal prompted a class-action suit against the company, which is still pending.

Seeking to overcome these setbacks, Bristol-Myers Squibb refiled the NDA for omapatrilat, including new data from its OCTAVE trial. To preserve the integrity of the NDA review, the company said it does not intend to publicly disclose OCTAVE data until the FDA has completed its review of the NDA submission.

The OCTAVE study was designed to compare the efficacy and safety in hypertension of two medicines (enalapril and omapatrilat) over 24 weeks of treatment. The company chose the option of keeping the study blinded until all patients completed their 24 weeks of therapy, rather than unblinding the data at an interim point. After the end of the 24-week period, the data for all patients were completed and, according to analysts, the supportive results from this data analysis formed the basis of the company's refiled NDA.

According to industry analysts, these data will define the drug's future. Even without angioedema, the drug's side-effect profile (including flushing and facial redness) could limit uptake if physicians judge this would hinder compliance.

Vanlev's potential, according to analysts, also will be impacted by how well Bristol-Myers Squibb educates physicians. The company would not provide comment on its marketing plans for the drug, nor did Robert A. Becker Euro RSCG Group, the healthcare agency of record for the product.

"General practitioners will have heard rumors about the angioedema and that will need to be addressed," says Nicola Maidwell, Ph.D., a research analyst with Decision Resources Inc., which puts Vanlev sales estimates at \$1.8 billion alone for hypertension in 2010. "That estimate is just one scenario that we modeled using our proprietary market forecasting tool the IFT (Interactive Forecasting Tool) — those optimistic sales figures are

based on the fact that all the newly submitted data from the OCTAVE trial show that the angioedema side effect is resolved and is at acceptable limits and will have a premium price higher than ACE inhibitors and angiotensin II antagonists. Specialists interviewed in our study said they would be relatively happy to prescribe Vanlev to patients based on the fact that the blood-pressure leveling effect is better than ACE inhibitors.

"If the angioedema isn't resolved with the lower doses being used in the OCTAVE trial, then the use of Vanlev is going to be severely restricted to patients with very resistant hypertension and/or congestive heart failure," she says. "That means sales of Vanlev will be compromised and if restricted to this population, we expect Vanlev to capture approximately 3% of prescriptions for hypertension, which equates to \$650 million in sales in 2010. With this scenario, the sales that would have gone to Vanlev will go to angiotensin II antagonists, such as Novartis' Diovan."

Dr. Weber says Bristol-Myers Squibb will need to implement an efficient and comprehensive physician education program to counter the publicity generated by the company's withdrawal of Vanlev's NDA, and the resulting concerns over safety.

"Bristol-Myers Squibb started an educational program about 18 months ago before it withdrew the drug's NDA," Dr. Weber says. "This drug will be approved in a setting where a lot of doctors will be watching closely."

Dr. Maidwell says, "Bristol-Myers Squibb is going to have to get out there and sell the concept. The specialists are very excited about this drug, but the general practitioners will be a harder group to convince."

## Meeting patient needs

"Bristol-Myers Squibb has a strong marketing infrastructure," Mr. Saftlas says. "If the company gets a good label, Vanlev could do a couple hundred million dollars the first year out, without too much sweat. Even if Vanlev is approved with a limited label, the hypertension market alone means that the drug will have sizeable sales."

Hypertension, or high blood pressure, affects 600 million people worldwide. Three of four people with high blood pressure in the U.S. have not attained the generally recom-

mended target of lower than 140 (systolic) and 90 (diastolic) mmHg and remain at higher risk for heart attack, stroke, heart failure, and kidney disease.

According to data from Scott-Levin's Source Prescription Audit, the total hypertension market for 2001 was valued at \$14.9 billion, including branded and generic treatments, an increase of 8.5% from 2000. Pfizer's calcium channel blocker Norvasc led the market in U.S. sales (\$1.77 billion) followed by AstraZeneca's ACE inhibitor Zestril (\$910.6 million), and Pfizer's ACE inhibitor Accupril (\$563.4 million).

Looking down the road, Front Line Strategic Consulting analysts predict that the market for hypertension treatments will reach \$38.5 billion by 2006, of which 15% is projected to be from sales of emerging products, including vasopeptidase inhibitors, launched between 2002 and 2006 (See box on page 56).

Front Line Strategic Consulting predicts that worldwide sales of Vanlev will be about \$700 million in 2003 and close to \$2.5 billion by 2006, provided the drug is launched in the fourth quarter of 2002.

"The hypertension market is huge and physicians are clamoring for innovation due to the large unmet need," Dr. Maidwell says. "The physicians we interviewed for our report unanimously want good blood-pressure lowering drugs and they don't have it in any single drug at the moment. They often have to prescribe a combination of agents, and that severely compromises patient compliance. Physicians are very excited about the dual action of Vanlev. This represents a truly unique entrant to the field, a new therapeutic class, and in our most optimistic scenario could generate sales equal to 8% of market share by 2010."

### The next stage

Front Line Strategic Consulting analysts identified other novel mechanism drugs that are expected to play a significant role in the market in the next 10 years, including selective aldosterone antagonists (SAAs), also known as SABs — selective aldosterone blockers — and renin inhibitors (RIs).

Pharmacia Corp. announced in February 2002 that the FDA accepted its NDA for eplerenone for the treatment of hypertension. Eplerenone is a SAB being developed for once-daily oral therapy designed specifically to block the effects of the hormone aldosterone.

Novartis' oral renin inhibitor, SP100, would be the first in a new class of hypertensive treatments. Novartis is expected to begin Phase III trials shortly.

Aventis Pharma's vasopeptidase inhibitor 100240 is entering Phase IIb clinical trials based on its effect of lowering blood pressure. It is a potential monotherapy for hypertension and congestive heart failure.

Bristol-Myers Squibb has a second-generation vasopeptidase inhibitor in development, BMS 189921, which is in Phase II clinical trials to treat hypertension and Phase I clinical trials to treat congestive heart failure.

In addition, Bristol-Myers Squibb has high hopes for Vanlev in other therapeutic areas. Along with hypertension, the company is investigating the drug's effectiveness as a treatment for congestive heart failure, a multibillion dollar market.

"This is crucial," Dr. Weber says. "The uptake of Vanlev for hypertension will be driven by the drug's clinical benefits beyond just lowering blood pressure. For example, if evidence from the OVERTURE study (for heart failure) shows that Vanlev is superior to the ACE inhibitors in preventing strokes and heart attack and Vanlev becomes the drug of choice for people with congestive heart failure, that will help drive physicians' acceptance."

Dr. Maidwell predicts key players will jostle for market position. With the top-selling ACE inhibitors Vasotec, Zestril, and Accupril facing patent expirations within two years as well as the calcium channel blocker Norvasc expected to lose patent protection in 2007, Merck, AstraZeneca, and Pfizer all are at risk of losing market share.

Pfizer is seeking to safeguard its position in this arena by extending the life of its Norvasc brand. Pfizer gained a six-month patent extension for its drug based on additional clinical experience in a pediatric population.

### A new frontier

Nancy Zhang, Ph.D., managing consultant, Front Line Strategic Consulting, and co-author of a new anti-hypertensive market report, says direct-to-consumer advertising will be the real challenge for companies wanting to expand their market share for their anti-hypertensive medications.

"There has not been a DTC push for anti-hypertensive drugs, such as that in the anti-cholesterol market," Dr. Zhang says. "One of the biggest hurdles that these companies will face as they bring these new drugs to market is patient education and increasing patient compliance.

"Patients know the cholesterol-lowering drugs, and ask for one over another," Dr. Zhang says. "In hypertension, patients don't know what options are available and they don't know what they should be asking for. So the company that does a good job at patient education and direct-to-consumer advertising will have a large impact on how it does in the marketplace." ♦

PharmaVoice welcomes comments about this article. E-mail us at [feedback@pharmalinx.com](mailto:feedback@pharmalinx.com).

## Experts on this topic

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