

NOVARTIS AG  
Form 6-K  
December 04, 2003

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## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### FORM 6-K

#### REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13A-16 OR 15D-16 OF THE SECURITIES EXCHANGE ACT OF 1934

Report on Form 6-K for the month of November 2003  
(Commission File No. 1-15024)

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### Novartis AG

(Name of Registrant)

Lichtstrasse 35  
4056 Basel  
Switzerland

(Address of Principal Executive Offices)

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F:  Form 40-F:

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes:  No:

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes:  No:

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes:  No:

Enclosures:

1. Novartis presents new corporate guidelines on human rights (Basel, November 27, 2003)
- 2.

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Novartis' 2003 "R&D day" (Basel, 17 November 2003)

3. Landmark Diovan® (valsartan) mega-trial proves life-saving benefits for heart attack sufferers (Orlando, Florida, 10 November 2003)
4. Medicines for Malaria Venture and Novartis agree to develop a pediatric formulation of Coartem® (Basel 10 November 2003)
5. Novartis signs license agreement to develop and globally commercialize cancer-compound Gimatecan from Sigma-Tau (Basel, 6 November 2003)

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

### **Novartis presents new corporate guidelines on human rights**

*Company supports the Universal Declaration of Human Rights and reinforces commitment to the UN Global Compact*

Basel, November 27, 2003 Novartis today confirmed its support for the Universal Declaration of Human Rights and announced new corporate human rights guidelines to meet its public commitments under the UN Global Compact.

"While it is clear that states have the leading role in the protection of human rights, business can and must play a complementary and constructive role in society to preserve basic human dignity," said Novartis Chairman and CEO Daniel Vasella. "Our new guidelines will help ensure that Novartis respects human rights and will not knowingly benefit from violations committed by third parties."

The result of more than two years of internal discussion and external dialogue with leading human rights organizations, the new guidelines define human rights as an integral part of Novartis' policy on corporate citizenship. The new guidelines define specific principles related to equal opportunity and non-discriminatory treatment, rights of personal security and employee rights. They also set forth positions regarding respect for national sovereignty, respect for local communities and indigenous peoples, and the protection of intellectual property and technology transfer.

"I wish to acknowledge the positive role that Novartis has played in promoting the value of the UN Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights," said Mary Robinson, former UN High Commissioner for Human Rights.

The new guidelines were introduced at the annual international symposium of the Novartis Foundation for Sustainable Development, which brought together nearly 500 experts and activists from around the globe to discuss the topic of 'Human Rights and the Private Sector'. The day-long session included presentations by human rights leaders including Mary Robinson, Executive Director of the Ethical Globalization Initiative; Irene Khan, Secretary General of Amnesty International; Jody Kollapen, Chair of the South African Human Rights Commission; and Micheline Calmy-Rey, Head of the Swiss Federal Department of Foreign Affairs. Noted economists Paul Streeten, Professor Emeritus of Economics at Boston University, and Lee Tavis, Professor of Economics at Notre Dame University, also contributed to a candid and open discussion about the role of corporations, governments and NGOs in protecting human rights.

In his remarks at the symposium, Dr. Vasella focused on how Novartis and other companies contribute to the protection of human rights mainly by pursuing their core business activities, practicing good corporate citizenship and supporting special projects to address important societal needs.

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"Our most significant contribution is driven by our success in discovering, developing and successfully marketing effective and innovative medicines," Dr. Vasella said. "By creating products that are useful and valuable to society, we are able to help patients and physicians, create jobs and ensure that shareholders receive an appropriate return on their investment."

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Through its corporate citizenship guidelines, Novartis makes additional contributions to the protection of human rights by assuming social and environmental responsibilities beyond the basic standards set by local laws and regulations. For example, the company pays a 'living wage' to employees in least-developed or developing countries and offers free access to HIV/AIDS, tuberculosis and malaria diagnosis and treatment for employees and their immediate family.

Finally, the company supports specific programs and activities to promote economic, social and cultural human rights. Through the new Novartis Institute for Tropical Diseases in Singapore, the company is pursuing scientific research on new drugs for the treatment of neglected diseases that disproportionately impact the poor, including major killers like tuberculosis and dengue fever. Through the long-standing efforts of the Novartis Foundation for Sustainable Development, the company also supports programs to improve prevention, treatment and other basic healthcare services in least-developed and developing countries. Novartis also donates free medication for leprosy patients worldwide and has made a new anti-malarial drug available to the WHO at cost. Finally, Novartis has created patient support programs through which needy cancer patients or uninsured senior citizens in developed countries have access to suitable medication.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of CHF 32.4 billion (USD 20.9 billion) and a net income of CHF 7.3 billion (USD 4.7 billion). The Group invested approximately CHF 4.3 billion (USD 2.8 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 78 200 people and operate in over 140 countries around the world. For further information, please consult <http://www.novartis.com>

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For more background information and pictures please consult  
[http://novartis.imagedirector.net/album\\_code=uaci137hrrq7](http://novartis.imagedirector.net/album?album_code=uaci137hrrq7).

For more information on the Novartis Foundation for Sustainable Development please consult  
<http://www.novartisfoundation.com>.

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

### To the Editors

#### Novartis' 2003 "R&D day"

Basel, 17 November 2003

On Wednesday, 19 November 2003 Novartis will present its pharmaceutical pipeline to the media and financial community at its annual "R&D day" event in New York.

There will be a press release at 05:30 CET followed by a live virtual press conference (in English) from New York starting at 14:00 CET and ending at approximately 14:45 CET. This will be webcast on [www.novartis.com](http://www.novartis.com) and can be heard via a telephone conference facility for journalists. The call-in numbers will be published with our press release and together with final details on [www.novartis.com](http://www.novartis.com). The presentation slides for the virtual press conference will be published on [www.novartis.com](http://www.novartis.com) approximately one hour beforehand so that you can download them in advance.

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Thomas Ebeling, CEO of Novartis Pharma AG, Joerg Reinhardt, worldwide Head of Development, and Mark Fishman, worldwide Head of Biomedical Research, will give short presentations on our Pharmaceuticals R&D pipeline. Following this, journalists will be able to ask them questions on the event over the phone or by email.

The slides and webcast playback will be available on [www.novartis.com](http://www.novartis.com) after the event. The sound track will also be available as a recording after the event via the call-in facility.

With kind regards  
Novartis Communications

### 19. November 2003 schedule overview

05:30 CET (23:30 EST, 18 November):	Press release
13.00 CET (07.00 EST):	Presentation slides for virtual media conference published on <a href="http://www.novartis.com">www.novartis.com</a>
14.00 - 14.45 CET (08.00 - 08.45 EST):	<b>Virtual media conference</b> live from New York on <a href="http://www.novartis.com">www.novartis.com</a>

Dial-in numbers Will be provided in the press release on November 19<sup>th</sup>

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### Investor Relations Release

#### Landmark Diovan® (valsartan) mega-trial proves life-saving benefits for heart attack sufferers

*Diovan is the only cardiovascular agent ever demonstrated by a head-to-head trial to have all the proven benefits of an ACE inhibitor, captopril, in patients following a heart attack.*

*VALIANT further strengthens the profile of Diovan in cardiovascular disease across key standard of care measures like cardiovascular protection, tolerability, blood pressure lowering efficacy and patient persistency with therapy!*

Orlando, Florida, 10 November 2003 The fastest-growing branded high blood pressure treatment in the world, Diovan® (valsartan), is also a potentially life-saving treatment after a heart attack, according to the findings of VALIANT, a major new study announced today at the American Heart Association Scientific Sessions 2003 and published online in the *New England Journal of Medicine*. VALIANT (VALsartan In Acute myocardial iNfarcTion) is the largest long-term study ever conducted in people who have survived a heart attack. This critical new data set helps establish Diovan as a highly desirable and powerful first-line option for an increasingly wide patient population.

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"We are very pleased with the results of the VALIANT trial, which showed that Diovan is the first and only angiotensin II receptor blocker (ARB) proven to be as cardioprotective as the current standard of care following a heart attack. When these data are combined with the strong benefits Diovan provides for blood pressure lowering, excellent tolerability and long-term patient persistency with therapy, they are very compelling for patients as well as physicians," said Joerg Reinhardt, Head of Development, Novartis Pharma AG. Novartis plans to file very soon for a post-MI indication.

Based on VALIANT and the cumulative clinical evidence being gathered for Diovan in hypertension, Novartis will accelerate clinical programs designed to demonstrate that Diovan has important blood pressure lowering, patient compliance and vascular health benefits beyond ACE inhibitors (angiotensin-converting-enzyme inhibitors).

"We believe Diovan is well on its way to becoming the new standard of care and we are committed to its continued success," added Reinhardt.

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VALIANT provides important new answers to clinical questions

A rigorous head-to-head comparison of Diovan against captopril, VALIANT studied 14 703 patients at the highest risk for death following a heart attack (myocardial infarction) for an average of two years. VALIANT also studied the effects of combination treatment with Diovan and the ACE inhibitor in these patients.

VALIANT demonstrated that Diovan has all the established life-saving benefits of captopril in heart attack patients and was at least as effective as the ACE inhibitor in reducing cardiac events following a heart attack, including repeat heart attacks and hospitalisations for heart failure. Diovan is the only cardiovascular agent ever demonstrated by a head-to-head trial to have all of the proven benefits of an ACE inhibitor in patients following a heart attack. No added benefits were seen with combination treatment.

"VALIANT was a major international study that will change treatment guidelines," said Marc Pfeffer, MD, PhD, the chair of the VALIANT study, who is a Professor of Medicine at Harvard Medical School and Senior Physician at Brigham and Women's Hospital, Boston. "We have proven that valsartan is as effective as an ACE inhibitor at prolonging life and preventing recurrent heart attacks and hospitalisations for heart failure. This is significant because it provides physicians with a new option for treating high-risk heart attack survivors."

Approved for the first-line treatment of high blood pressure in more than 80 countries and for heart failure in more than 40 countries, Diovan is the most widely prescribed drug in its class and the fastest growing branded high blood pressure treatment in the world. VALIANT now demonstrates Diovan is an effective option for first-line treatment of high-risk patients following a heart attack.

The co-chair of VALIANT is John McMurray, MD, Professor of Medical Cardiology and Honorary Consultant Cardiologist, Clinical Research Initiative in Heart Failure, University of Glasgow. Data coordination and analysis for VALIANT was conducted at Duke Clinical Research Institute, Durham, North Carolina, under the direction of Robert M. Califf, MD, Director of the Institute and Associate Vice Chancellor for Clinical Research, Duke University Medical Center.

### **Diovan reduces risk for premature death after heart attack by 25%**

An active-control trial, VALIANT compared Diovan to a proven treatment instead of placebo or sugar pill. VALIANT was designed and statistically powered to prove whether the effects of Diovan on all-cause mortality were comparable to captopril. Its patient population and dosing regimen were intentionally modelled after studies which established the benefits of ACE inhibitors vs. placebo so that a statistical comparison (imputed placebo analysis) could be made of their findings.

"VALIANT demonstrates Diovan preserved 99.6% of the benefits of captopril, meaning it reduced death to the same degree as the proven treatment," said Professor McMurray. "This finding translates into a 25% reduction in premature death by Diovan in patients at high risk following a heart attack." Diovan could potentially save 30,000 new lives in the US and 15 000-20 000 new lives in the EU each year.

The findings of VALIANT were consistent across all study endpoints and patient subgroups, regardless of age, gender, race, co-existing medical conditions (e.g. diabetes), or background medications, including beta blockers. While no further benefits were seen in patients who took combination therapy, there was no added mortality and no added cardiovascular morbidity in patients who took a beta blocker with Diovan in combination with the ACE inhibitor.

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VALIANT demonstrates that Diovan is well-tolerated in post-heart attack patients. In VALIANT, discontinuations due to adverse events were lowest in the valsartan group and highest in the combination group. Hypotension and renal side effects were limited in number and most

common in the group that received both medications together than in either group receiving valsartan or captopril alone. The rate of hypotension and renal dysfunction was slightly higher in the valsartan group than in the captopril group. Reducing the dose of study drug allowed a majority of patients who experienced hypotension or renal dysfunction to continue on study medication, and thus remain on life-saving therapy. Overall, there was a statistically significant higher rate of patient discontinuations due to adverse events in the captopril group, where more treatment-limiting side effects occurred, including cough, rash and taste disturbance, compared to the valsartan group.

VALIANT was a prospective, multinational, randomised, active-controlled, parallel group trial conducted at 931 centres in 24 countries. Patients were men and women aged 18 and over (not of child-bearing potential) enrolled between 12 hours and 10 days after they suffered a heart attack complicated by temporary (transient) heart failure and/or abnormal pumping of the heart (left ventricular systolic dysfunction). In addition to either Diovan and/or captopril, patients also received recommended background therapy including aspirin, cholesterol-lowering agents (statins) and beta blockers.

Because of its scope and design, ongoing analysis of the VALIANT data will continue to yield valuable new insight for years to come about the care of patients following a heart attack. In addition to the primary findings, five other abstracts based on VALIANT were also presented at the American Heart Association Scientific Sessions 2003 concerning topics ranging from factors contributing to poor outcomes following a heart attack to contemporary post-heart attack treatment patterns.

#### **About heart attack**

Heart attack remains one of the world's deadliest conditions. Every year, 600 000 people from EU countries and 1.1 million Americans suffer a heart attack. High blood pressure is a major risk factor for heart attacks.

While progress has been made in treating heart attacks in the emergency room, people who survive the acute (emergency) phase of a heart attack have permanently damaged hearts and are at greatly increased risk for repeat attacks, heart failure, or other deadly complications. One in three dies within a year after surviving a first heart attack. Half of all heart attacks are repeat attacks.

#### **More than 50 000 patients involved in clinical studies with Diovan**

Diovan is one of the most widely studied cardiovascular agents in the world and the most widely studied ARB. The Diovan clinical research programme is designed to involve 50 000 patients, including 8000 patients with diabetes, in several major trials investigating potential new applications for Diovan across the cardiovascular continuum from pre-diabetes (impaired glucose tolerance) to heart failure. Val-HeFT (Valsartan Heart Failure Trial), which remains one of the largest studies ever conducted in heart failure, led to the approval of Diovan for use in this disease in more than 40 countries. The next trial to report will be VALUE (Valsartan Antihypertensive Long-Term Use Evaluation), a study of 15 314 hypertensive patients with at least one additional risk factor for cardiovascular events. Another major ongoing study with Diovan is NAVIGATOR (Nateglinide and Valsartan in Impaired Glucose Tolerance Outcomes Research) trial in 9150 pre-diabetes patients at risk for cardiovascular events. Novartis is also conducting VAL-MARC, a study of the effects of Diovan on CRP (c-reactive protein) in 5610 high blood pressure patients. CRP is a strong, independent predictor of cardiovascular risk.

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The foregoing release contains forward-looking statements that can be identified by terminology such as "increasingly," "if successful," "attempt," "impute," "will file," "expected," "suggest," "investigating," "potential," "new applications," or similar expressions, or by discussions regarding potential new indications or labelling for Diovan, or regarding the long-term impact of a patient's use of Diovan. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Diovan to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Diovan will be approved for any additional indications or labelling in any market. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding commercialisation of Diovan could be affected by, among other things, additional analysis of Diovan clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; and other risks and factors referred to in the Company's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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Wogen, J. et al.: Journal of Managed care Pharmacy 2003; 9:424-9

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Publication of the study results can be viewed online at [www.nejm.org](http://www.nejm.org)

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Medicines for Malaria Venture and Novartis agree to develop a pediatric formulation of Coartem®**

*New partnership will help combat drug-resistant malaria, a disease that is killing 3 000 children a day.<sup>1</sup>*

Basel 10 November 2003 Novartis and Medicines for Malaria Venture (MMV), a not-for-profit organization, today signed an agreement to jointly develop a pediatric formulation of Coartem®, a breakthrough in treatment-resistant malaria.

Malaria is one of the leading causes of death in the developing world, killing more than one million people every year.<sup>2</sup> The majority of victims are in Africa where a child dies every 30 seconds from the disease.<sup>1</sup> In sub-Saharan Africa, 71% of deaths occur in children below the age of five.<sup>3</sup> By the age of one, the average child in high-transmission areas of Africa has contracted three life-threatening malaria infections.<sup>4,5,6</sup> However, less than half of all African children under five who are infected with malaria are treated with an antimalarial medicine.<sup>7,8</sup>

"With this new agreement MMV and Novartis will align and accelerate efforts to bring modern drug innovation to a population that desperately needs it the millions of infants suffering unacceptably high malaria-induced morbidity and mortality" said Dr. Christopher Hentschel, Chief Executive Officer of MMV. "This drug will likely be the most effective treatment for young children who are by far the most vulnerable victims of this ancient but now resurgent disease."

Coartem, consisting of artemether and lumefantrine, is the first and only fixed artemisinin-based combination therapy, or ACT, for uncomplicated falciparum malaria available worldwide. Because the malaria parasite has become resistant to most traditional treatments, the World Health Organization now recommends that countries adopt ACT when there is strong evidence that existing conventional medicines are no longer working. This combination of artemether and lumefantrine is on the WHO's Essential Medicines list. Novartis is making Coartem available at cost to developing countries under a public-private partnership with the WHO to improve access to the lifesaving therapy.

"This partnership with MMV signals our commitment to the global fight against malaria," said Dr. Daniel Vasella, Chairman and CEO of Novartis. "We believe the most promising way to help increase access to life-saving therapies to the poorest people in the world is by working with partners such as MMV and the WHO with whom we already cooperate in the fight against malaria and leprosy."

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"Malaria has a devastating impact on children, their families and the communities in which they live," said Dr. Fatoumata Nafou-Traoré, Executive Secretary of the Roll Back Malaria Partnership Secretariat, which coordinates the work of the global partnership, founded by the WHO, UNICEF, the United Nations Development Program and the World Bank, which now includes a diverse range of committed organizations. "New public-private partnerships for research, development and delivery of effective treatments are essential in fighting the disease."

A pediatric formulation would be easier for children to take and improve compliance, ensuring the drug's efficacy. Development of the new pediatric formulation is already underway and a clinical trial is expected to commence during the third quarter of next year. The target date for launch of the new formulation is 2007.

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### About MMV:

Medicines for Malaria Venture (MMV) was officially launched on 3 November 1999 as a nonprofit foundation dedicated to reducing the burden of malaria in disease endemic countries by discovering, developing and delivering new affordable antimalarials through effective public-private partnership. After four years of operation, MMV is managing the largest portfolio of malaria research in history with 21 Projects in different stages of drug research and development. For further information please consult <http://www.mmv.org>.

### About Novartis:

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of USD 20.9 billion and a net income of USD 4.7 billion. The Group invested approximately USD 2.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 78 500 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

Background material and pictures can be found at:

[http://novartis.imagedirector.net/album code=z4ncw67vppb9](http://novartis.imagedirector.net/album?album_code=z4ncw67vppb9)

### Today's media event will be accessible via conference call:

**Type:** Dial-In Conference Call in English. Presentations followed by a Q&A session.

**Dial-In number:** +41 91 610 5600

**Playback:** The playback will be available 1 hour after the conference call for 48 hrs.  
Participants requesting the Digital Playback will be dialing:  
+41 91 612 4330 (in Europe and Africa)  
+44 207 866 4300 (in UK)  
+1 877 344 7529 (in USA)  
and will be asked to enter **the ID 640** followed by the # sign.  
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### References

1. World Health Organisation. *Expert Committee on Malaria: Twentieth Report* (2000). WHO Technical Report Series 892.
2. Bremen, J. *The ears of the hippopotamus: manifestations, determinants, and estimates of the malaria burden*. Am. J. Trop. Med. Hyg 2001; 64(1,2)S, 1-11.
3. World Health Organisation. *Roll Back Malaria Advocacy Guide* WHO/CDS/RBM/2000.26:11-12.
4. Najera JA, Hemple J. *The burden of malaria*. WHO CTD/MAL/96.10,1996.



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5. Murray CJL, Lopez AD. *The global burden of disease: A comprehensive assessment of mortality and disability from diseases, injuries and risk factors in 1990 and projected to 2020*. Harvard School of Public Health, Harvard University Press, 1996.
6. Greenwood BM *et al*. *Mortality and morbidity from malaria among children in rural areas of the Gambia, West Africa*. Transactions of the Royal Society of Tropical Medicine and Hygiene 1987; 81(3): 478-473.
7. Breman JG, Campbell CC. *Combating severe malaria in African children*. Bulletin of the World Health Organization, 1988, 66(5):611-620.
8. Holtz TH *et al*. *Health care seeking behaviour and home treatment of febrile illness in Blantyre District, Malawi, 2000*. American Society of Tropical Medicine and Hygiene, 50<sup>th</sup> Annual Meeting November 11-15, 2001, Atlanta, GA: abstract 536.

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#### Investor Relations Release

### Novartis signs license agreement to develop and globally commercialize cancer-compound Gimatecan from Sigma-Tau

#### *Oral Topoisomerase I inhibitor in Phase II development expands Novartis' leading Oncology pipeline*

Basel, 6 November 2003 Novartis Pharma AG has signed an agreement with Sigma-Tau of Rome, Italy, for the rights to develop and commercialize Gimatecan, a next generation oral topoisomerase I inhibitor in Phase II development for the treatment of common solid tumors.

Preclinical data and early clinical results for Gimatecan have shown anti-tumor activity. The data also suggest the compound is well-tolerated, with reduced side effects such as diarrhea, which can limit effective dosing for other cytotoxic drugs. Phase II trials are underway in a variety of cancers. The medicine is administered orally, with the potential to further ease cancer patients' burden.



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