CW Weekly
A CenterWatch Publication

January 30, 2006

Breaking News and Market Intelligence for the Clinical Trials Industry

Parexel shares surge…2

Quintiles in Asian joint venture…2

Maximax Launches as Global CRO

Maximax International, based in Michigan, has launched as a global contract research organization (CRO).

The startup claims operations already in more than 25 countries across five continents and strong teams to support customers. Maximax International intends to become one of the leading players in this industry in North America, South America, Asia, Central and Eastern Europe, Western Europe and North Africa.

"The project has been in the working for more than two years and led by a network of entrepreneurial medical doctors and business individuals. We selected a market positioning strategy to start with certain size and capabilities and avoid a strategy of slow growth from very small new entrant and grow your way up. We have well experienced teams in place who all have several years of experience in the drug development industry. While we did not purchase any CRO, we worked and are working with small CROs—partners in several global locations as investors/partners," Max Rashed, president and chief executive officer of Maximax, told *CWWeekly*.

Maximax International has already successfully completed round one financing to support marketing and sales. Through the

page 3

AAIPharma Transforming into Private CRO

Wilmington, N.C.-based AAIPharma is opening a new phase I facility in the Research Triangle Park area in North Carolina as it continues its remaking as a contract research organization (CRO).

The transformation of the former troubled specialty pharmaceutical company into a CRO will move ahead again next month when it becomes a private company as it is expected to emerge from bankruptcy. The company's shares are currently traded over-the-counter.

The new phase I clinic will increase the company's phase I capacity in the U.S. This clinic, which is complemented by the company's 65-bed phase I unit in Germany, will focus on bioequivalence trials in support of their customers' aNDA programs. It will also provide the company with the infrastructure to strengthen and expand its clinical pharmacology operation in support of our customers' new drug programs. AAIPharma's clinical research group includes the former MTRA in Natick, Mass., where it retains an office.

The company now has about 850 employees and is bolstering its leadership with new hires. AAIPharma appointed two new executives to lead and expand the company's clinical operations worldwide. Dr. George Perentesis will head up AAI-Pharma's North American clinical

page 3

Company Profile. . . 4
An interview with Alfonso Alanis, chairman and chief executive officer **Anaclim**

Drug & Device Pipeline News. . . 6
CenterWatch has identified 36 drugs and devices that have entered new trial phases this week.

Trial Results. . . 7
CenterWatch reports on results for five drugs. Visit www.centerwatch.com for real-time updates on drugs in clinical trials.

Biotech Review. . . 8
Biotech briefs from *Bioworld Today*.

Volume 10, Issue 05.

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Industry Briefs

CROs

- **Parexel** continues its comeback and its shares surged last week to new 52-week highs. While the company's second-quarter net income dropped 17%, it beat analyst expectations for earnings per share. Parexel reported second quarter earnings of $5 million, or 19 cents a share, down from $6.1 million, or 23 cents a share in the prior year's quarter. Parexel recorded revenue of $183.5 million, an increase of 8.2% from $169.6 million. Second quarter operating margin was 7.1%, compared with 5.5% in the year ago quarter. The company said its U.S. business continues to be a drag on earnings. On a segment basis, consolidated service revenue for the second quarter was $108.9 million in clinical research services, $27.2 million in consulting and marketing services, and $13.7 million in Perceptive Informatics.

- **Quintiles** has signed an agreement for a joint venture to commercialize pharmaceutical products in the Asia Pacific region. Quintiles' partners in the joint venture, which will have an investment fund totaling $112 million, are Asia Pacific pharmaceutical services group **Interpharma Asia Pacific**, parent of drug distributor **Zuellig Pharma**; and Asia investment company Temasek Holdings Limited. In June 2005, the companies announced the joint venture and Quintiles' signing of a letter of intent to join it. Each partner is expected to make an equal investment in the joint venture and own one-third of the company. Quintiles will transfer its Innovex contract sales businesses in Australia, South Korea and India, including approximately 800 employees, to the joint venture. These Innovex businesses provide commercialization expertise and resources to pharmaceutical and biotechnology companies in these countries and New Zealand. In addition, the agreement calls for Quintiles to be the exclusive provider of clinical development services required by the joint venture in countries where Quintiles has operations providing those services. PharmaLink, the Asia Pacific pharmaceutical marketing services division of Interpharma, will be transferred to the new joint venture and will help in the acquisition of these products and, together with the transferred Innovex businesses, subsequent marketing in the Asia Pacific healthcare market. Zuellig Pharma will provide distribution and logistics expertise on a contract basis; Temasek brings overall knowledge of the Asia Pacific healthcare market and investing to meet its needs. The joint venture will be managed by Brian Nichols, chief executive officer of PharmaLink.

- **MDS Pharma Services** has been selected as the preferred CRO of the **Multiple Myeloma Research Consortium** (**MMRC**). MDS Pharma Services will manage multiple MMRC pre-clinical and clinical research efforts, including data management related to the MMRC's tissue collection program.

CenterWatch Information Services

The CenterWatch Monthly
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CenterWatch Clinical Trials Listing Service™
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Features (continued from page 1)

Maximax International

United States Securities and Exchange Commission, under Regulation D in North America and Regulation S in Europe, Maximax International organized a private offering of securities for nine North American and four European investors.

The company's management team includes Sam Abueita, Ph.D., member of the Board of Directors and Treasurer; Steven Cala, Ph.D., Director, Bio-Statistics; Rayonne Caesar-Chavannes, MBA/HCM, BSc, Director, Sales and Marketing & North America Operation; Stan Edlavitch, Ph.D., Executive Director, Scientific Affairs; Joanne Faycurry, Member of the Board of Directors, chair of Legal Affair Executive Committee; Tel Ganeson, MS, Director, Projects Management; John Ghesquiere, M.D., Director, North America; George Kuzmanovski, MBA, Director, Data Management; Hassen Hammoud, Ph.D., Executive Director, Six Sigma; Shahid Jamil, M.D., Executive Director, Mid Asia and Middle East; Raj Kapoor, Ph.D., Member of the Board of Directors, Chair of Quality Control and Quality; Feng Li, M.D., Director, China and North America; Dorothy Nelson, Ph.D., Executive Director, North America; Heather Palmer, Ph.D., Director, North America; Bonita Pedrosi, MS, Director, North America; Vasile Piticas, MS, Member of the Board of Directors representing European investors; Marc Rich, MBA, Secretary of the Board of Directors; Asa Shani, MBA, Director, Sales and Marketing; Judy Trepeck, CPA, Member of the Board of Directors, chair of Financial Affairs and Strategy Executive Committee; Ehab Kamal, MS, Director, GCC region; Gokhan Goktug, Ph.D, Director, Turkey; Krystof Jankowski, PhD, Director, BRP region; Jan Zuchelkowski, M.D., Director, Canada; George Nicola, M.D., Director, Western Europe; Nadia Zvartau, M.D., Ph.D., Director, Russia and Ukraine; Gassan Traya, M.D., Director, Brazil; . Josef Kolman, DDS, Director, Central Europe; Pavel Istok, M.D., Director, Central Europe; Kamal Shazly, M.D., Director, Egypt; Emna Kotran, DDS, Director, Tunis, Ali Ben Omar, M.D., Director, Morocco; Lata Ganesen, M.D., Director, India;. Roderick Meer, Director, Pacific Rim; and Boyan Doganov, M.D., Director, Bulgaria.

"We are one of the few CROs, if not maybe the only CRO, who is locally supporting their customers in several good locations for clinical research, such as Trinidad, Morocco, Brazil, Egypt, Bangladesh, Tunisia. We have strong teams in Michigan and Toronto, Poland, Romania and Bulgaria," Rashed said.

He expects the company will grow rapidly. "We trust that this market is very healthy and require additional players who bring expertise in process, operation and global business and we believe we have a strong team to support this need," Rashed said.

AAIPharma

operations. Dr. Brian O'Keeffe will lead its European Clinical Operations.

"Both Dr. Perentesis and Dr. O'Keeffe will significantly strengthen our company's global clinical capability," said Dr. Ludo Reynders, president and chief executive officer of AAIPharma. "The expansion of our phase I capacity and the strengthening of our global clinical operations are important steps in our strategy to reposition the company as a strong global drug development company."

In fiscal year 2005, AAIPharma reported $77 million in sales.

Profile: Minority-Focused Contract Research Organization

Anaclim Indianapolis, Indiana

An interview with Alfonso Alanis, chairman and chief executive officer

Year founded: 2005
Employees: 12 F-T; 2 contractors; 2 interns
Telephone: (317) 275-9100
Email: aalanis@anaclim.com
Web site: www.anaclim.com

What are the challenges to recruiting minorities into clinical trials and how will you address them?

There are a lot of myths about why minorities do not participate in clinical trials. But, a recent study by the NIH, published this month in PLoS Medicine, looked at a significant number of clinical trials where ethnicity was reported. What they found was that ethnic minorities do want to participate in clinical trials and that there was very little difference in the willingness of minorities to participate compared with non-minorities. The problem is that they do not have access to clinical trials. As underrepresented as minority patients are, the underrepresentation of minority investigators is much worse. We know that minority patients tend to go to see minority physicians for the most part in the outpatient setting. So, our strategy has been to enroll minority investigators. We have created a large database of investigators who belong to ethnic minorities or who have a predominance of minority patients. We can tap into these investigators to participate in our clinical trials.

Why is minority inclusion in clinical trials important?

As costs of development of new drugs continue to escalate, you want to be more selective with the population of patients that you study. Also, as prices continue to be under pressure, what would you rather do? Go out and study thousands of patients for which the efficacy of a drug would be 20% or 30%? Or, would you rather select a subgroup of those patients for which the efficacy might be 70% and the trial you need to do is smaller because you have a higher efficacy rate and therefore the statistical power you have is higher and the size of the population that you need to do the study is smaller? As the pharmaceutical industry faces all these pressures on prices, on escalating costs, on intellectual property and on safety, they probably are going to have to be pushed to be more selective. We need to convince large pharmaceutical companies that it is in their best interest to study a population of patients that is representative of how the drug is going to be used. It baffles me that you would test a drug in one population of patients and then sell it to another. You're taking an exorbitant amount of risk and you have a lot of liability if something goes wrong. According to data from the U.S. census, in 2050, minorities will become the majority. That's the reality of the makeup of our country. You are either going to be pulled into addressing the issue or you're going to be on the front lines pushing to address the issue.

What is your vision for Anaclim?

One of the advantages of having worked for a major pharmaceutical company for a long time is that I have been on the other side of the table. I've heard all the excuses and all the bad news from CROs that I need to hear in my career. I have heard too many times that the study is going to cost more because we didn't consider this, that or the other thing. Perhaps the most dreaded news is that the quality of the study was compromised for whatever reason, or the eternal story that the enrollment is not going the way we planned and therefore we're going to take a hit on the timeline. We're very cognizant of the issues in general with the CRO industry. As we move forward with our strategy to bring ethnic minorities into clinical trials, we are spending a very large amount of time—as we should—to make sure the quality of the work is outstanding. I expect that the more successful I am with Anaclim, the more the other CROs are going to start to emulate us, which is perfectly fine because that will address the issue of minority participation in clinical trials, which is really what we've set out to do. I welcome that.

Drug & Device Pipeline News

Company	Drug/Device	Therapeutic Area	Status	Contact
Proacta	PR-104	solid tumors	Phase I trials initiated at two sites in Australia and one site in the U.S.	+649 363 3322 www.proactatherapeutics.com
Array BioPharma	ARRY-334543	cancer	Phase I trials initiated	(303) 381-6600 www.arraybiopharma.com
Arteriocyte	adult derived stem cells	chronic ischemia	Phase I trials initiated	(216) 658-3970 www.arteriocyte.com
Kosan Biosciences	KOS-1022 (DMAG)	advanced solid tumors	Phase I trials initiated at two sites in the U.S.	(510) 732-8400 www.kosan.com
Roche/MorphoSys AG	HuCAL	Alzheimer´s disease	Phase I trials initiated in Europe	+41-61-688 1111 www.roche.com
GroPep	PV903	infertility	Phase Ia trials initiated enrolling 36 subjects at one site in Australia	61 (0)8 8354 7700 www.gropep.com.au
CepTor Corporation	Myodur	Duchenne muscular dystrophy	Phase I/II trials planned	(410) 527-9998 www.ceptorcorp.com
Proacta	PR-104	solid tumors	Phase I trials initiated in New Zealand, Australia and the U.S.	+649 363 3322 www.proactatherapeutics.com
Erimos	EM-1421	solid tumors	Phase I trials initiated enrolling 30 subjects across three U.S. sites	(713) 541-2000 www.erimos.com
Genta	Genasense (oblimersen)	advanced cancers	Clinical trials initiated	(908) 286-9800 www.genta.com
ProlX	PX-12	gastrointestinal cancers	Phase Ib trials initiated and will enroll 38 subjects at one U.S. site	(520) 622-5552 www.prolx.com
ConjuChem	PC-DAC:Exendin-4	type 2 diabetes	Phase I/II initiated enrolling up to 68 subjects	514) 844-5558 www.conjuchem.com
Migenix	MX-3253	hepatitis C infections	Clinical trials planned	(604) 221-9666 www.migenix.com
CytRx	arimoclomol	amyotrophic lateral sclerosis	Phase II extension trials planned	(310) 826-5648 www.cytrx.com
Stem Cell Therapeutics	NTx-265	stroke	Two phase II trials planned	(403) 245-5495 www.stemcellthera.com
Polydex Pharmaceuticals	Cellulose Sulphate (Ushercell)	bacterial vaginosis	Phase II trials planned and will enroll 60 women at one site in Brazil	(242) 322-8571 www.polydex.com
Threshold Pharmaceuticals	glufosfamide + gemcitabine	pancreatic cancer	Phase II trials planned and will enroll 28 subjects	(650) 474-8200 www.thresholdpharm.com
DURECT Corporation	SABER-Bupivacaine	post-operative pain relief	Phase II trials initiated in the U.S.	(408) 777-1417 www.durect.com
EntreMed	MKC-1	metastatic breast cancer	Phase II trials initiated across 15 sites in the U.S.	(240) 864-2600 www.entremed.com

Drug & Device Pipeline News

(continued from page 5)

Company	Drug/Device	Therapeutic Area	Status	Contact
Xanthus Life Sciences	Symadex	metastatic colorectal cancer	Phase II trials initiated enrolling 49 subjects in Europe	(617) 225-0522 www.xanthus.com
PTC Therapeutics	PTC124	Duchenne muscular dystrophy	Phase II trials initiated enrolling 24 subjects	(908) 222-7000 www.ptcbio.com
Polydex	Ushercell (cellulose sulfate)	bacterial vaginosis	Phase II trials initiated enrolling 60 subjects one Brazilian site	(242) 322-8571 www.polydex.com
Pharmos	cannabinor	pain and autoimmune diseases	Phase IIa trials planned	(732) 452-9556 www.pharmoscorp.com
DELEX Therapeutics	AeroLEF	moderate to severe acute pain	Phase IIb trials initiated enrolling 120 subjects	(905) 629-9761 www.delextherapeutics.com
Gentium	defibrotide	veno-occlusive disease	Phase II/III trials initiated enrolling 270 subjects at 30 sites	+39 0 3138 5217 www.gentium.it
Clinical Data	vilazodone	major depressive disorder	Phase III trials initiated enrolling 400 patients at eight U.S. sites	(617) 527-9933 www.clda.com
Cardiogenesis Corporation	PMC procedure	transmyocardial revascularization	IDE cleared, medical device trials planned	(714) 649-5000 www.cardiogenesis.com
BioCryst Pharmaceuticals	peramivir	Influenza	Fast Track status granted	(205) 444-4600 www.biocryst.com
Nuvelo	alfimeprase	peripheral arterial occlusion	Fast Track status granted	(650) 517-8000 www.nuvelo.com
SuperGen	Orathecin (rubitecan)	pancreatic cancer	MAA withdrawn	(925) 560-0100 www.supergen.com
Pfizer	Sutent (sunitinib)	gastrointestinal stromal tumors	FDA approved for additional indication	(212) 733-2323 www.pfizer.com
Chiron/Cubist	Cubicin (daptomycin)	complicated skin and soft-tissue infections	EU approved	(510) 655-8730 www.chiron.com
Serono	Gonalef (follitropin alfa, recombinant)	male hypogonadism	Approved in Japan	+41 2 2739 3000 www.serono.com
Novartis	Femara (letrozole)	postmenopausal breast cancer	Approved in Japan	+41 6 1324 1111 www.novartis.com
Kissei	Urief	benign prostatic hypertrophy	Approved in Japan	+81 (0)2 6325 9081 www.kissei.com
Collagen Matrix	Collagen-Mineral Composite Bone Graft	bone repair	510(k) clearance	(201) 405-1477 www.collagenmatrix.com

Trial Results

Neurology

- **Javelin Pharmaceuticals** issued preliminary results of a phase IIb trial of **Dyloject** (**diclofenac sodium injection**) for the treatment of pain. Trial data met their primary efficacy endpoint, producing significant, linear-dose-response pain relief over six hours, as measured on the Visual Analog Scale. This response was superior to placebo and non inferior to approved therapy with Ketorolac. The drug experienced superior onset of pain relief after five minutes, compared to Ketorolac, on both the Visual Analog and Categorical scales. This randomized study enrolled 353 patients with moderate-to-severe post-surgical pain, who received single administrations of one of five doses of the drug (up to 75 mg), an approved regimen of IV Ketorolac (30 mg), or placebo.

- **Axonyx** reported positive results of a phase I trial of **Posiphen** for the prevention of Alzheimer's disease progression. The drug yielded a positive safety profile, with no serious adverse events reported and a good overall tolerability profile. Peak serum drug concentrations exceeded those predicted in animal models to be efficacious in affecting beta-amyloid metabolism. This double-blind, placebo controlled study enrolled 60 healthy volunteers, who received one of five single doses of Posiphen (10 mg, 20 mg, 40 mg, 80 mg or 160 mg) or placebo.

- **Avicena** reported results of a phase I/II trial of **HD-02**, for the treatment of Huntington's disease (HD), in the journal *Neurology*. Results from the study indicated that serum levels of 8-hydroxy-2'-deoxyguanosine (8OH2'dG), an HD disease biomarker, were significantly reduced in patients receiving the drug. Safety and tolerability results were generally positive, and after drug-free washout, serum creatine levels had returned to baseline. This multi-center, double-blind, placebo-controlled study enrolled 64 patients, who were randomized to receive 8 g HD-02 or placebo daily for 16 weeks, followed by an eight week drug washout.

Respiratory

- **LAB International** issued positive results of a phase I trial of **LAB CGRP** (**calcitonin gene related peptide**), for the treatment of asthma. Results of the study were positive, with no clinically significant changes in safety measures, including laboratory values, heart rate, blood pressure or ECG at any trial dose. The drug was shown to dose-dependently increase circulating CGRP levels at the 1 mg and 5 mg dose. The lower two trial doses did not significantly increase peptide levels. Additional pharmacokinetic values showed rapid absorption (31 to 125 pg/ml peak concentration range). This randomized, double-blind, placebo-controlled dose escalating study enrolled 10 healthy volunteers, who received one of four single inhaled doses of the drug (0.025 mg, 0.1 mg, 1.0 mg or 5.0 mg) or placebo.

Oncology

- **Biovest International**, a subsidiary of **Accentia Biopharmaceuticals**, reported follow-up data from a phase II trial of **BiovaxID**, a personalized anti-tumor vaccine for the treatment of mantle cell lymphoma. Data from the 46-month (3.8-year) follow-up to a phase II study yielded an overall survival rate of 89%; this compared favorably to historical survival rates of 50% at three years and 20% at five years. Further, BiovaxID induced anti-tumor T-cell lymphocyte responses in most patients, despite B-cell depletion due to chemotherapy. This single-arm, open-label study treated 23 patients with the drug following six cycles of EPOCH-R chemotherapy (a regimen which includes rituximab).

Biotech Review

From *BioWorld Today*

- Forging ahead with its lupus drug, **Prestara**, **Genelabs Technologies** has decided to conduct another phase III trial, and likely will look for a development partner to help offset costs. During a recent meeting with the FDA, the agency told Genelabs that an additional pivotal trial would be needed to support the drug's approval as a treatment for the signs and symptoms of systemic lupus erythematosus. At the same time, the Redwood City, Calif.-based company decided not to pursue Prestara in the prevention of bone mineral density loss in lupus patients, despite receiving an approvable letter for that indication in 2002, based on results from a nested phase III study showing that patients receiving Prestara had increased mean bone mineral density (BMD) of the lumbar spine and hip compared to decreased BMD in the placebo group.

- Early clinical testing could get easier, or at least more accessible, if product sponsors take note of recent **FDA** communications. New guidance documents that have been released by the agency detail its willingness to let researchers evaluate new drugs in humans with fewer regulatory hurdles—or with more flexibility—before filing an investigational new drug application. According to **Karen Mahoney**, a spokeswoman for the FDA's Center for Drug Evaluation and Research, the documents clarify existing regulations and make no changes. The FDA's "Exploratory IND Studies" guidance explains a process for beginning human studies before phase I, the standard period for safety testing. The result, the agency believes, will lead to more efficient drug development because ineffective candidates would wash out more quickly, while those with better efficacy would move forward.

- Shares of **Dynavax Technologies** jumped 34% Jan. 19, after the company reported two-year data from a phase II/III trial showing that its disease-modifying allergy drug, **Tolamba**, significantly reduced symptoms compared to placebo.

  Shares of Dynavax (NASDAQ:DVX) climbed $1.48 to close at $5.83.

  The trial randomized 462 patients into three arms: those receiving six weekly injections of Tolamba prior to the 2004 August to October ragweed allergy season, those receiving the same injections plus a booster before the 2005 season, and those on placebo. The drug met its primary endpoint, showing that patients in the Tolamba-treated group had a statistically significant reduction in total nasal symptoms vs. placebo.

- **Avigen** is expanding its portfolio by way of an in-licensing deal that brings in **tolperisone** (**AV650**), a small molecule for disabling neuromuscular conditions, further distancing itself from its past as a gene therapy firm. In the past year, the Alameda, Calif.-based company made "a strategic and complete shift to focus on neurology and pain," said Michael Coffee, its chief business officer.

- Following word of a potential $300 million deal with **AstraZeneca**, **Targacept** is trying again for an initial public offering, with hopes of raising as much as $59.8 million, though the number of shares and price per share have not been specified. Although the use of proceeds was not broken down by amount per project, Winston-Salem, N.C.-based Targacept said cash from the IPO would finance completion of the phase I trial and a phase II study of **TC-2696**, the product for acute postoperative pain, as well as studies to support an investigational new drug application for **TC-2216**, along with phase I and phase II trials testing the compound in depression and anxiety disorders.

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Thomson NexCura

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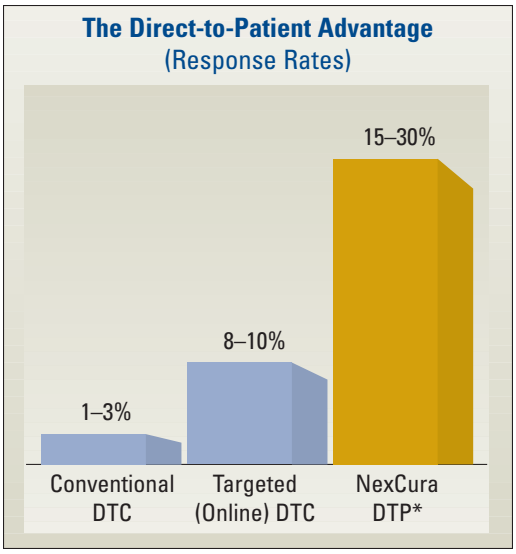

*Typical response rates calculated from 12 recent DTP campaigns conducted for 9 clients.

Messages delivered through NexCura are:

- Permission-based; 70-80% of users of NexCura® *NexProfiler*™ treatment option tools opt-in to receive clinical trial information
- Associated with credible, trusted sources of information reflected in NexCura's Web Partners who include major health education and advocacy organizations and leading clinics
- Managed securely, efficiently and accurately through NexCura's proprietary methods and technology
- Used by major pharmaceutical and medical-device companies, with proven success

To learn more about Thomson NexCura and their Direct-to-Patient Communication Services, visit www.nexcura.com, call us at (877) 422-3228 or fill out the form on the back of this flyer to have a business development representative contact you.

Fax Back Form

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