



STN is operated in North America  
by Chemical Abstracts Service.

## STN Database Summary Sheet

The **PHAR File (Pharmaprojects)** contains drug marketing, R&D, and licensing information about pharmaceutical products under development in the world's major markets since 1980. The products are predominantly new chemical compounds, but also include biotechnology products and novel formulations. Products whose development has been discontinued or for which there is no evidence of continuing development are also included in the file.

Each record in the file is a report on a single product and contains all or some of the following information: the product name, synonyms, originating company and development status, a summary of the most recent information added, licensees and their development status, stage of development in up to 40 countries, major event history, Pharmaprojects' proprietary product rating, rigorously classified therapeutic activity, routes of administration, indications and status, pharmacokinetics, origin of material, chemical structure, chemical name (conforming to CAS(R) index name format where possible), CAS Registry Number, molecular formula, pharmacology and patent/priority data, and descriptive text with key literature references. For new products, the text is in sections divided into marketing, clinical, preclinical, and licensing information.

### Subject Coverage

- |                 |                 |                            |                         |
|-----------------|-----------------|----------------------------|-------------------------|
| – Allergies     | – Economics     | – Manufacturers            | – Pharmacology          |
| – Biochemistry  | – Genetics      | – Medicine                 | – Physiology            |
| – Biology       | – Health        | – Microbiology             | – Research Institutions |
| – Biotechnology | – Immunology    | – Nutrition                | – Research Projects     |
| – Business      | – Institutions  | – Pathology                | – Toxicology            |
| – Chemistry     | – Life Sciences | – Pharmaceutical Chemicals |                         |

### Sources

The Pharmaprojects editorial team is committed to constant investigation and evaluation of pharmaceutical R&D around the world and uses the widest possible range of sources. Information is collected from scientific meetings, *Scrip World Pharmaceutical News* (also published by Informa UK Ltd.), company web sites, online news agencies and press releases, direct company communications, conference abstracts, and journals. Each year, all companies in Pharmaprojects are invited to update their entries to ensure that the information is completely up-to-date and accurate. Wherever possible, the companies are contacted randomly throughout the year.

### File Data

- 1980-present
- More than 45,000 records (9/09)
- Updated weekly
- Automatic current-awareness searches (SDIs) may be run weekly or monthly (weekly is the default)

### User Aids

- Therapeutic Activity Codes in PHAR
- STNGUIDE
- Online Helps (HELP DIRECTORY lists all help messages available)

### Database Producer/Supplier

Informa UK Ltd.  
Telephone House  
69-77 Paul Street  
London  
EC2A 4LQ  
UK  
Phone: (+44) (0)20 7017 5000  
Fax: (+44) (0)20 7017 6905  
E-mail: [pharmaprojects.enquiry@informa.com](mailto:pharmaprojects.enquiry@informa.com)  
Web: <http://www.pharmaprojects.com>

#### In North America

CAS  
STN North America  
P.O. Box 3012  
Columbus, Ohio 43210-0012 U.S.A.

CAS Customer Care:  
Phone: 800-753-4227 (North America)  
614-447-3700 (worldwide)  
Fax: 614-447-3751  
E-mail: [help@cas.org](mailto:help@cas.org)  
Internet: [www.cas.org](http://www.cas.org)

#### In Europe

FIZ Karlsruhe  
STN Europe  
P.O. Box 2465  
76012 Karlsruhe  
Germany  
Phone: +49-7247-808-555  
Fax: +49-7247-808-259  
E-mail: [helpdesk@fiz-karlsruhe.de](mailto:helpdesk@fiz-karlsruhe.de)  
Internet: [www.stn-international.de](http://www.stn-international.de)

#### In Japan

JAICI (Japan Association for  
International Chemical Information)  
STN Japan  
Nakai Building  
6-25-4 Honkomagome, Bunkyo-ku  
Tokyo 113-0021, Japan  
Phone: +81-3-5978-3601 (Technical Service)  
+81-3-5978-3621 (Customer Service)  
Fax: +81-3-5978-3600  
E-mail: [support@jaici.or.jp](mailto:support@jaici.or.jp) (Technical Service)  
[customer@jaici.or.jp](mailto:customer@jaici.or.jp) (Customer Service)  
Internet: [www.jaici.or.jp](http://www.jaici.or.jp)

**PHAR****Search and Display Field Codes**

The field that allows left truncation (/BI) is marked with an asterisk (\*).

Search Field Name	Search Code	Search Examples	Display Codes
Basic Index * (contains single words from text (TX), chemical name (CN), company name (CO), development status (DSTA), classification code (CC), controlled term (CT), pharmacokinetic information (PHK), pharmacological activity code (PHCD), origin of material (ORGM), route of administration (RTE), revision note (RNTE), market rating (MRAT), novelty rating (NRAT), speed of development rating (SRAT), total aggregate rating (TRAT), and linked activity table (LN) fields, as well as molecular formulas (MF) and CAS Registry Numbers (RN))	None (or /BI)	S 38304-91-5 S LAUNCH? S ?KINASE? S UPJOHN S NEW PATENT S DERMATOL? (A) FORMUL? S APPETITE STIMULANT S INHALED S BIOLOGICAL(L)AUTOLOGOUS S C9H15NO4 S CHA-K-AG S NOVELTY (L) PRECLINICAL S CANCER (S) BREAST	CC, CN, CO, CT, DSTA, LN, MF, MRAT, NRAT, ORGM, PHCD, PHK, RN, RNTE, RTE, SRAT, TRAT, TX
Accession Number Chemical Name	/AN /CN	S 521/AN S ROGAINE/CN S BENZAMIDE?/CN	AN CN
Classification Code (Therapeutic Descriptor and Code)	/CC	S D11Z/CC S ANTIACNE/CC S BLOOD FRACTION/CC	CC, LN
Company Name (contains parent company name, originator or licensee type, country, and some ISO country codes)	/CO	S (CELLTECH (L) ORIGINATOR)/CO S (TAISHO (L) LICENSEE)/CO S SRI INTERNATIONAL/CO S THERAPEUT?(L)UNITED KINGDOM/CO S ABBOTT/CO (L) PRECLINICAL	CO
Controlled Term (Indication)	/CT	S CHRONIC FATIGUE SYNDROME/CT S CHEMOTHERAPY?/CT(L)CLINICAL TRIAL	CT
Correction Date (1) (minor corrections) Development Status (2)	/CDAT /DSTA	S CDAT>=20010501 S (LAUNCHED (L) BE)/DSTA S PRECLINICAL/DSTA S US/DSTA S CANCER (L) PHASE II?/DSTA	Not displayed CO, DSTA, LN
Development Status Code (2) Document Number Entry Date (1) Field Availability (code and text)	/DSTC /DN /ED /FA	S L/DSTC S 008008/DN S L1 AND ED>=20010100 S RN/FA S L1 AND PHK/FA	LN DN Not displayed Not displayed
Freely Rotatable Bonds (1,10) Gene Name Hydrogen Acceptor (1,10) Hydrogen Donor (1,10) Last Change Date (1) Launch Year (1,3) LOGP (1,10) Market Size Rating (4) (code and text)	/FRB /GEN /HAC /HD /LCDAT /LNY /LOGP /MRAT	S 2-5/FRB S TOPOISOMERASE II/GEN S 4/HAC S 3/HD S 19990205/LCDAT S 1998/LNY S LOGP>=3 S L1 AND 500/MRAT S L1 AND 3/MRAT	FRB GEN HAC HD LCDAT DSTA LOGP MRAT
Market Size Rating Number (1,4) Molecular Formula (5)	/MRR /MF	S MRR>=3 S C9H15N5O/MF S C9 H15 N5 O/MF S C21H25NO4 . HCL/MF	MRAT MF
Molecular Weight (1,10) New Chemical Entity	/MW /NCE	S 110-125/MW S YES	MW NCE

## Search and Display Field Codes (cont'd)

Search Field Name	Search Code	Search Examples	Display Codes
Novelty Rating <b>(4)</b> (code and text)	/NRAT	S L2 AND NEW FORMULATION/NRAT S L2 AND 4/NRAT	NRAT
Novelty Rating Number <b>(1,4)</b>	/NRR	S 3-4/NRR	NRAT
Number of Components <b>(1)</b>	/NC	S NC>=2	Not displayed
Origin of Material (code and text)	/ORGM	S NP/ORGM S NP-A/ORGM S NATURAL PRODUCT?/ORGM S NATURAL PRODUCT, ANIMAL/ORGM	ORGM
Patent Country (code and text)	/PC	S US/PC	PI
Patent Number	/PN	S US4139619/PN	PI
Periodic Group	/PG	S B6/PG	Not displayed
Pharmacokinetic Information <b>(6)</b>	/PHK	S (HUMAN(L)BIOAVAILABILITY)/PHK	PHK
Pharmacological Activity Code	/PHCD	S CHA-K-AG/PHCD S PERM-AG/PHCD S TRYPSIN?/PHCD	LN, PHCD
Priority Country (code and text)	/PRC	S JP/PRC	PRAI
Priority Date <b>(1)</b>	/PRD	S 20001105/PRD	PRAI
Priority Year <b>(1)</b>	/PRY	S 1999/PRY	PRAI
Revision Date <b>(1)</b>	/RDAT	S 19990100-19990400/RDAT S JAN-MAR 1999/RDAT S L1 AND RDAT>=20010100	RDAT
Revision Note <b>(7)</b>	/RNTE	S 22071-15-4 AND NEW CHEMICAL STRUCTURE/RNTE S (NEW THERAPEUTIC ACTIVITY (L) HORMONAL)/RNTE S NEW LICENSEE/RNTE(L)RDAT>20010100 S (NEW PRODUCT (L) ACTUAL)/RNTE	RNTE
Route of Administration (code and text)	/RTE	S P/RTE S P-IV/RTE S PARENTERAL?/RTE S PARENTERAL, INTRAVENOUS/RTE S PHARMAPROJECTS/SO	RTE
Source <b>(8)</b>	/SO	S 7/S	SO
Specific Element Count <b>(1)</b>	/Element Symbol		MF
Speed of Development Rating <b>(4)</b> (code and text)	/SRAT	S DEVELOPMENT "NOT" STARTED/SRAT S 1/SRAT	SRAT
Speed of Development Rating Number <b>(1,5)</b>	/SRR	S 2-3/SRR	SRAT
Status <b>(9)</b> (type and code)	/STA	S ACTIVE/STA S FULLY LAUNCHED/STA S L/STA	STA
Total Aggregate Rating <b>(4)</b> (code and text)	/TRAT	S L5 NOT UNAVAILABLE/TRAT S L5 AND 4/TRAT	TRAT
Total Aggregate Rating Number <b>(1,4)</b>	/TRR	S TRR>=5	TRAT
Update Date <b>(1)</b>	/UP	S L1 AND UP>=20030100	UP

**(1)** Numeric search field that may be searched with numeric operators or ranges.

**(2)** Stages of development that are recognized are PRECLINICAL (P) (all stages of pharmacological and toxicological development before clinical trials begin), PHASE I CLINICAL TRIAL (C1) (volunteer studies), PHASE II CLINICAL TRIAL (C2) (clinical studies to establish efficacy), PHASE III CLINICAL TRIAL (C3) (large-scale clinical trials), CLINICAL TRIAL (C) (clinical studies, phase unknown), PRE-REGISTRATION (PR) (registration documents submitted but not yet approved), REGISTERED (R) (products approved by regulatory authorities but not yet in the general market), LAUNCHED (L) (available in the market and advertised), SUSPENDED (S) (development temporarily suspended pending further decision), NO DEVELOPMENT REPORTED (N) (no evidence of continuing development), DISCONTINUED (development ceased), and WITHDRAWN (W) (removed from the marketplace after launch has taken place). Licensing offers are designated by the phrase AVAILABLE FOR LICENSING, following the country name. The most advanced stage of development a product has reached anywhere in the world is included in this field with the term WORLD.

**(3)** The launch year appears for most, but not all, substances that have been launched.

## PHAR

### Search and Display Field Codes (cont'd)

- (4) See HELP RATINGS for more information on the rating systems.
- (5) Formulas may not be in Hill order.
- (6) Only the data in the Model and Parameter columns of the PHK field are searchable.
- (7) Major events that occur in pharmaceutical R&D may be searched in this field. New events added in March 2000: NEW CHEMICAL STRUCTURE (identifies whether a chemical structure has been applied to the profile or when the structure information changes due to a change in lead compound); NEW THERAPEUTIC ACTIVITY (identifies when a drug's use or potential is extended); NEW INDICATION (identifies when a drug's use or potential is extended); ORPHAN DRUG STATUS GRANTED (identifies drugs with market exclusivity for drugs under development for minority diseases); STATUS REVERSION (identifies drugs that are forced to return to an earlier stage of development). New event added in September 2002: NEW PHARMACOLOGICAL ACTIVITY (highlights when a new mode of action of a drug is discovered or identified).
- (8) The source for all documents in PHAR is Pharmaprojects. Informa UK Ltd., Richmond, Surrey, UK.
- (9) The three status types are ACTIVE (A), CEASED (C), and FULLY LAUNCHED (L). Products in the FULLY LAUNCHED category are ones that have already been launched in most major markets of the world or that may not be introduced in any further markets.
- (10) In addition to searching specific properties, you may also enter LIPINSKI/CALC (or LIP/CALC) as a shortcut for searching the Lipinski "rule of five" properties and their values. The LIP/CALC term is expanded into the following search query: 0-5/HD AND 0-10/HAC AND LOGP<=5 AND 0-500/MW.

### Super Search Fields (1)

Enter a super search code to execute a search in one or more fields that may contain the desired information. Super search fields facilitate crossfile and multifile searching. EXPAND may not be used with super search fields. Use EXPAND with the individual field codes instead.

Search Field Name	Search Code	Fields Searched	Search Examples	Display Codes
Patent Countries (code and text) Patent Numbers	/PCS /PATS	/DS, /FC, /PC /FN, /PN	S US/PCS S US4139619/PATS	PI PI

- (1) Enter a super search code to execute a search in one or more fields that may contain the desired information. Super search fields facilitate crossfile and multifile searching. EXPAND may not be used with super search fields. Use EXPAND with the individual field codes instead.

### DISPLAY and PRINT Formats

Any combination of formats may be used to display or print answers. Multiple codes must be separated by spaces or commas, e.g., D L1 1-5 CN CO. The fields are displayed or printed in the order requested.

Hit-term highlighting is available for all fields except AN, CO, LN, PHK, STF, STR, and STS. Highlighting must be on during SEARCH in order to use the HIT, KWIC, and OCC display formats.

Format	Content	Examples
AN (1)	Accession Number	D 2 AN CN DSTA
CC	Classification Code (Therapeutic Descriptor and Code) (includes LN)	D CC
CN	Chemical Name	D CN
CO	Tabular display of Company Type (Originator or Licensee), Company Name, Country, and Development Status	D CO CN
CT	Controlled Term (Indication)	D CT
DN	Document Number	D AN DN
DSTA	Development Status (list of countries and status in each country) (includes CO)	D DSTA 1-3
ED	Entry Date	D ED
FRB	Freely Rotatable Bonds	D FRB
GEN	Gene Name	D GEN
HAC	Hydrogen Acceptor	D HAC
HD	Hydrogen Donor	D HD
LCDAT	Last Change Date (date, editor initials, summary of last change)	D LCDAT RNTE
LN	Tabular display of linked activity listing Therapy (CC), Pharmacology (PHCD), and Status (DSTC) Codes	D LN
LOGP	LOGP	D LOGP
MF	Molecular Formula	D CN MF

## DISPLAY and PRINT Formats (cont'd)

Format	Content	Examples
MRAT MW NCE NRAT ORGM PHCD PHK  PI (PN, PATS) PRAI (APPS, PRN) RDAT (RNTE) RN RTE SO (2) SRAT STA STF (3) STR (4) STS (3,4) TRAT TX (AB) UP WSTA (3)	Market Size Rating Molecular Weight New Chemical Entity Novelty Rating Origin of Material Pharmacological Activity Code (includes LN) Tabular display of Pharmacokinetic Information listing linked Model and Parameter data, and displayable Values and Units Patent Information Priority Information Revision Date and Revision Note CAS Registry Number Route of Administration Source Speed of Development Rating Status Flat Structure Diagram (no stereo bonds indicated) Structure Diagram (includes stereo bonds and R/S/E/Z labels when available) Stereo Structure (includes stereo bonds when available) Total Aggregate Rating Text Update Date World Status	D MRAT D MW D NCE D NRAT D ORGM D 2,4,6 PHCD D PHK  D PI D PRAI  D RDAT IDE D RN L2 1-5 D RTE D SO 1 3 5 D SRAT D STA TX D STF D CN STR D CN STS D TRAT D TX STD D UP D WSTA
ALL (4)  IDE (4) SCAN (6) STD (4)  TRIAL (FREE TRI) (1,5)	AN, DN, ED, CN, RN, MF, NCE, STA, CO, PI, PRAI, SO, TX, DSTA, CC, CT, ORGM, RTE, RDAT, RNTE, PHCD, PHK, LN, NRAT, MRAT, SRAT, TRAT, LCDAT, STR (ALL is the default) AN, DN, ED, CN, RN, MF, NCE, STA, STR CN (random display, no answer numbers) AN, DN, ED, CN, RN, MF, NCE, STA, CO, PI, PRAI, DSTA, CC, CT, ORGM, RTE, RDAT, RNTE, PHCD, PHK, LN, NRAT, MRAT, SRAT, TRAT, STR CN (International Non-proprietary Name (INN))	D ALL  D IDE D SCAN D STD  D 1-10 TRIAL
HIT KWIC OCC (1)	Fields containing hit terms Hit terms plus 20 words on either side (KeyWord-In-Context) Number of occurrences of hit terms and fields in which they occur	D HIT D KWIC D OCC 1-6

(1) There is no online display fee for this format.

(2) The source for all documents in PHAR is Pharmaprojects. Informa UK Ltd., Richmond, Surrey, UK.

(3) Custom display only.

(4) Stereo structure diagrams are available only on graphics terminals, in offline prints, or when using STN Express with *Discover!* or STN on the Web.

(5) Only the INN name is displayed. If other names are available, they are displayed with the CN format.

(6) SCAN must be specified on the command line, i.e., D SCAN or DISPLAY SCAN.

**PHAR****SELECT, ANALYZE, and SORT Fields**

The SELECT command is used to create E-numbers containing terms taken from the specified field in an answer set.

The ANALYZE command is used to create an L-number containing terms taken from the specified field in an answer set.

The SORT command is used to rearrange the search results in either alphabetic or numeric order of the specified field(s).

Field Name	Field Code	ANALYZE/ SELECT (1)	SORT
CAS Registry Number	RN	Y (2)	N
CAS Registry Number and Chemical Name	CHEM	Y (2)	N
Chemical Name	CN	Y (default)	Y
Classification Code (Therapeutic Descriptor and Code)	CC	Y	N
Company Name	CO	Y (3)	Y
Controlled Term (Indications)	CT	Y	Y
Development Status	DSTA	Y	N
Development Status Code	DSTC	Y (3)	N
Document Number	DN	N	Y
Entry Date	ED	Y	Y
Freely Rotatable Bonds	FRB	N	Y
Gene Name	GEN	Y	Y
Hydrogen Acceptor	HAC	N	Y
Hydrogen Donor	HD	N	Y
Last Change Date	LCDAT	Y	N
Licensee	LICENSEE	N	Y
LogP	LOGP	N	Y
Market Size Rating	MRAT	Y	Y
Molecular Formula	MF	Y	N
Molecular Weight	MW		N
Novelty Rating	NRAT	Y	Y
Occurrence Count of Hit Terms	OCC	N	Y
Origin of Material	ORGM	Y	Y
Originator	ORIGINATOR	N	Y
Patent Country	PC	Y (3)	Y
	PCS	Y (3)	N
Patent Information	PI	Y (4)	Y
Patent Number	PN	Y	Y
	PATS	Y (5)	N
Pharmacokinetic Information	PHK	Y (6)	N
Pharmacological Activity Code	PHCD	Y	N
Priority Country	PRC	Y	Y
Priority Date	PRD	Y	Y
Priority Information	PRAI	N	Y
Priority Number	PRN	N	Y
Priority Year	PRY	Y	Y
Revision Date	RDAT	Y	N
Revision Note	RNTE	Y	N
Route of Administration	RTE	Y	Y
Speed of Development Rating	SRAT	Y	Y
Status	STA	Y	Y
Text	TX	Y (2)	N
Total Aggregate Rating	TRAT	Y	Y
Update Date	UP	Y	Y

(1) HIT may be used to restrict terms extracted to terms that match the search expression used to create the answer set, e.g., SEL HIT CN.

(2) Appends /BI to the terms created by SELECT.

(3) SELECT HIT and ANALYZE HIT are not valid with this field.

(4) Selects or analyzes the patent number with /PN appended to the terms created by SELECT.

(5) Selects or analyzes the patent number with /PATS appended to the terms created by SELECT.

(6) Selects or analyzes only the data in the Model and Parameter columns.

## Sample Records

### DISPLAY ALL

DISPLAY ALL  
 AN 27937 PHAR  
 DN 008221  
 ED Entered STN: 23 April 2003 Last updated on STN: 23 April 2003  
 CN cefprozil  
 CN Arzimol  
 CN BMY-28100  
 CN Brisoral  
 CN Cefzil  
 CN Procef  
 CN Refzil O  
 CN 5-Thia-1-azabicyclo(4.2.0)oct-2-ene-2-carboxylic acid,  
 7-((amino(4-hydroxyphenyl)acetyl)amino)-8-oxo-3-(1-propenyl)-,  
 (6R-(6alpha,7beta(R\*))) - (CAS)  
 RN 92665-29-7  
 MF C18 H19 N3 O5 S  
 MW 389.43  
 HAC 7  
 HD 5  
 LOGP -.30  
 FRB 8  
 NCE YES  
 STA Fully Launched

### CO

Type	Company Name (Country)	Development Status
Originator	Bristol-Myers Squibb (United States)	Launched
Licensee	Bentley (United States)	Launched

PI GB 2173798  
 PRAI US 19850422  
 SO Pharmaprojects. PJB Publications Ltd., Richmond, Surrey, UK  
 TX Cefprozil is an orally-active cephalosporin, developed by Bristol-Myers Squibb (BMS) (Company communication, BMS, Apr 1986).

### Marketing

It is launched as Cefzil in the US (1992), Costa Rica, Guatemala, Honduras, Indonesia, Mexico, Peru, Venezuela (1993), Brazil, Colombia, Greece, Spain (1994), Canada (1995), the UK (1998), the Philippines, Singapore (1999), Argentina, China and South Korea for use in pharyngitis/tonsillitis, otitis media, acute bronchitis, acute bacterial exacerbation of chronic bronchitis, sinusitis, and uncomplicated skin and skin structure infection (Ann Rep, BMS, 1993; Company communications, BMS, Feb 1992 and Feb 1995; Pharm Prac, 1995, 11(10), 98; Company newslett, BMS, 1996, 7(3), 13). It is launched as Procef in Hong Kong, Israel, Portugal, Switzerland and Thailand (Scrip, 1997, 2252, 17). A generic version is launched as Refzil-O by Ranbaxy in India (Scrip Daily Online, 24 Feb 2003, S00790528). It is licensed to Laboratorios Belmac (Bentley) for Spain (Scrip, 1998, 2358, 12). It was additionally approved in the US for the treatment of acute bacterial sinusitis in adult and paediatric patients (Scrip, 1996, 2182, 21). It was awaiting registration as shown and an sNDA was filed in the US for paediatric pharyngitis (Company communications, BMS, Feb 1993 and Feb 1995).

**PHAR****DISPLAY ALL (cont'd)**

## Clinical

## Phase III

In clinical trials in adults with sinusitis, cefprozil was as effective as Augmentin but caused less diarrhoea (Scrip, 1996, 2182, 21). In 212 patients with skin infections given 500mg once-daily for 5-10 days, 93% had a satisfactory clinical response and 91% had microbial eradication (cf 92% and 89%, respectively, for cefaclor (qv) 250mg tid) (Clin Ther, 1992, 14, 458, PMID:1638587). Cefprozil was effective in 96% of 262 children with acute otitis media where recurrent infections included Streptococcus pneumoniae, Haemophilus influenzae and Moraxella catarrhalis (Scrip, 1996, 2192/3, 27). In 1597 patients with mild- to-moderate tonsillitis or pharyngitis, the efficacy of cefprozil once-daily or bid compared favourably cf penicillin, cefaclor and erythromycin (MIMS UK, Jul 1998, 6).

## Phase I

In healthy subjects, cefprozil po had a t<sub>1/2</sub>, V<sub>d</sub> and Cl of 1.3hr, 0.23l/kg and 3ml/min/kg, respectively. In 12 healthy volunteers, cefprozil 500mg po had a mean plasma T<sub>max</sub> of 1.5hr and a mean C<sub>max</sub> of 10.5microg/ml (Pharmacy Network Group Web Page, 26 Aug 2003). Updated by CH on 2/9/2003.

## Additional Clinical Information

## Phase III

In a Phase III trial in 479 patients with uncomplicated maxillary sinusitis, 250 and 500mg bid cefprozil had clinical response rates of 80 and 83%, respectively, cf 78% for amoxicillin/ clavulanate. Both cefprozil doses produced better gastrointestinal tolerance than amoxicillin/clavulanate (Infections Med, 1997, (Suppl) 61, 1).

In a multicentre, randomized clinical trial in 161 patients with acute bacterial exacerbations of chronic bronchitis or secondary bacterial infections of acute bronchitis, 250mg bid cefprozil achieved a satisfactory clinical outcome in 91.1% of evaluable patients cf 93.9% with cefuroxime axetil (250mg bid). The eradication rates for cefprozil and cefuroxime axetil were 79 and 82%, respectively. Against Gram positive pathogens, however, they were 94 and 63%, respectively. Both treatments were well tolerated (Infections Med, 1997, (Suppl) 51, 0).

In a multicentre, randomized, open-label trial in 175 patients with acute bacterial exacerbations of chronic bronchitis, 500mg bid for 10 days cefprozil achieved a satisfactory clinical response in 88.3% cf 88.6% with clarithromycin (500mg bid x 10 days). Pathogen eradication rates of cefprozil and clarithromycin were 77.3 and 78.9%, respectively. Cefprozil was well tolerated, significantly more likely to cause taste perversion and stomach-related adverse events (Infections Med, 1997, (Suppl) 43, 0).

## DISPLAY ALL (cont'd)

DSTA World: Launched  
Argentina: Launched  
Belgium: Pre-registration  
Brazil: Launched 1994  
Canada: Launched 1995  
Chile: Pre-registration  
China: Launched  
Colombia: Launched 1994  
France: Phase III Clinical Trial  
Germany: Pre-registration  
Greece: Launched 1994  
Hong Kong: Launched  
India: Launched 2003  
Ireland: Pre-registration  
Israel: Launched  
Italy: Pre-registration  
Japan: Pre-registration  
Malaysia: Launched  
Mexico: Launched 1993  
Peru: Launched 1993  
Philippines: Launched 1999  
Portugal: Launched  
Korea, Republic of: Launched  
Spain: Launched 1994  
Sweden: Phase III Clinical Trial  
Switzerland: Launched  
Thailand: Launched  
United Kingdom: Launched 1998  
United States: Launched 1992  
Venezuela: Launched 1993

CC J1D1 Cephalosporin, oral

CT Indication: Infection, dermatological (Launched); Infection, respiratory tract, lower (Launched); Infection, respiratory tract, upper (Launched); Sinusitis (Launched); Otitis (Launched); Tonsillitis (Launched)

GEN Target Gene: Unspecified

ORGM CH-SY (Chemical, synthetic)

RTE A-PO (Alimentary, po)

RDAT 19991103 RNTE ##Estimated; Additional Launches The Philippines and Singapore  
19981015 ##Estimated; New Licensees Bentley  
19980815 ##Estimated; Additional Launches The UK  
19971015 ##Estimated; Additional Launches Thailand  
19960315 ##Estimated; Additional Launches Canada  
19950615 ##Estimated; Additional Registrations Switzerland  
19950515 ##Estimated; Additional Registrations Spain  
19920415 ##Estimated; First Launches The US  
19920215 ##Estimated; First Registrations The US  
19901115 ##Estimated; Registration Submissions Japan  
19890615 ##Estimated; Change in Status Phase III Clinical Trial  
19890615 ##Estimated; Names Granted BMY-28100

NRAT 2:Novelty Rating - Established Strategy  
MRAT 4:Market Rating - US\$ 5001-10000 million  
SRAT 4:Speed Rating - Faster than Average  
TRAT 10:Total Rating - Total Rating

PHCD SY-CW-AN; Cell wall synthesis inhibitor; Enzyme, Ligase, Cell wall synthesis inhibitor; Cell wall enzymatic synthesis inhibitor; Antimicrobial e.g. bacitracin, cephalosporin, cycloserine; Antimicrobial e.g. penicillin, vancomycin; E-LI-SY-CW-AN; 6.

PHCD E; E-LI; E-LI-SY; E-LI-SY-CW; E-LI-SY-CW-AN; E-SY; E-SY-CW; E-SY-CW-AN; E-CW; E-CW-AN; E-AN; LI; LI-SY; LI-SY-CW; LI-SY-CW-AN; LI-CW; LI-CW-AN; LI-AN; SY; SY-CW; SY-CW-AN; SY-AN; CW; CW-AN; E-LI-SY-AN; E-SY-AN; LI-SY-AN; E-LI-AN.

**PHAR****DISPLAY ALL (cont'd)**

PHK

Model	Parameter	Values	Units
Human (capsules)	t1/2	1.3	hr
Human (capsules)	Vd	0.23	l/kg
Human (capsules)	Cl	3	ml/min/kg
Human (500 mg capsules)	Tmax	1.5	hr
Human (500 mg capsules)	Cmax	10.5	microg/ml

LN

Therapy (CC) | Pharmacology (PHCD) | Status (DSTC)

J1D1 | SY-CW-AN | L

LCDAT 20030902: CH : Country statuses updated

