Intec Pharma Reports Fourth Quarter and Year End 2018 Financial Results and Corporate Update

February 27, 2019

JERUSALEM, Feb. 27, 2019 /PRNewswire/ -- Intec Pharma Ltd. (NASDAQ: NTEC) ("Intec" or "the Company") today announces financial results for the fourth quarter and year ended December 31, 2018 and provides a corporate update.

Highlights of the fourth quarter 2018 and recent weeks include:

- Reported positive data from a pharmacokinetic (PK) study of Accordion Pill™-Carbidopa/Levodopa (AP-CD/LD) 50/500 mg dosed three times per day (TID) in Parkinson's disease (PD) patients, which demonstrated AP-CD/LD met the primary endpoint of reducing plasma levodopa variability compared to standard oral CD/LD with statistical significance;
- Dosed first patient in a Phase 1 PK study of Accordion Pill-Tetrahydrocannabinol (AP-THC), which is evaluating a key component of cannabis for expected use in various pain indications;
- Announced that the Accordion Pill developed for a proprietary Novartis compound is continuing into a clinical PK study under the previously announced feasibility and option agreement with Novartis Pharmaceuticals;
- Reported completion of global enrollment in the pivotal Phase 3 ACCORDANCE clinical trial of AP-CD/LD for the treatment of advanced Parkinson's disease patients;
- Announced that more than 90% of eligible patients from the ACCORDANCE clinical trial are opting to participate in the Open Label Extension (OLE) study; and
- Changed SEC filing status from a Foreign Private Issuer to a U.S. Domestic Issuer, effective January 1, 2019.

Management Commentary

"We are very pleased with the corporate and clinical achievements we made throughout 2018. We believe these accomplishments form the foundation from which we expect to attain a number of key milestones in the coming year. We expect to have multiple clinical data readouts this year, including the topline results from our pivotal Phase 3 ACCORDANCE trial. In addition, we expect to continue to build our Accordion Pill drug delivery platform with the addition of both partner-sponsored R&D programs and internally-led drug reformulation programs," stated Jeffrey A. Meckler, Vice Chairman and Chief Executive Officer of Intec Pharma.

"We made significant progress with our most advanced asset on the Accordion Pill platform: the pivotal Phase 3 clinical development program of AP-CD/LD as a potential new baseline treatment for advanced Parkinson's disease patients. Most recently, we were very pleased to report favorable data from our PK study of AP-CD/LD 50/500 mg TID in Parkinson's disease patients. The data confirmed our expectations that AP-CD/LD 50/500 TID would reduce levodopa variability in PD patients, which can potentially reduce motor fluctuations in these patients. These PK data using the most common dose in our Phase 3 ACCORDANCE study are encouraging and support our confidence in this pivotal program for which we continue to expect topline data in mid-2019.

"During the fourth quarter we made significant progress advancing a number of key pre-commercial activities that should position us to file for regulatory submission and to support a commercial launch. In December 2018, the large commercial scale production line was delivered to our manufacturing partner, LTS LohmanTherapie-Systeme AG (LTS), in Andernach, Germany. We are in the process of installing and connecting all the ancillary equipment and expect to begin the validation, bioequivalency and stability studies needed for approval of our commercial production processes in the coming months. After preliminary discussions with the U.S. Food and Drug Administration in anticipation of filing for marketing approval of AP-CD/LD, we remain confident we are on track to submit a New Drug Application for approval of AP-CD/LD in mid- to late-2020, assuming positive topline data in mid-2019.

"Our commercial assessment and payor access work continues to support a robust and growing market opportunity for AP-CD/LD as a potentially best-in-class baseline therapy for advanced Parkinson's disease patients and this is also reflected in the increasing interest from potential commercial partners.

"During the past few months, we also made considerable progress advancing and expanding our AP platform by creating an innovative design that targets lymphatic absorption as a method of creating a unique PK profile. We were pleased to move forward our cannabinoid program with the dosing of the first patient in our Phase 1 PK study of AP-THC using a newly-designed Accordion Pill. We have completed the dosing of the AP-THC program and the data is in the process of being analyzed by a third-party Contract Research Organization per protocol. However, upon raw data review, the delivery of THC does not appear to meet our full program expectations. We await the full dataset and the statistical analysis to determine our next steps. Given the known analgesic properties of cannabinoids, we remain enthusiastic about the potential for these programs and believe our AP-cannabinoids will be applicable to a variety of pain indications.

"Another exciting development for our AP platform is the progress we made developing an AP for a Novartis propriety compound. Our Intec team successfully created a customized AP for Novartis' proprietary compound that met the required *in vitro* specifications set forth in our feasibility agreement. We mutually agreed to proceed with the program and plan to enter the clinic with a first-in-human PK study in the first half of 2019.

"We believe continued success with these newer programs further validates the platform, confirms our technical abilities to build custom APs and

paves the way for additional collaborative agreements. Importantly, these new programs offer the opportunity to pursue new additions to our intellectual property portfolio.

"We entered 2019 on strong footing and expect to build on that momentum throughout the balance of the year as we seek to monetize our late-stage asset in Parkinson's disease and invest in expanding the clinical development pipeline for our Accordion Pill platform in underserved medical indications with large market opportunities. We believe this two-pronged strategy offers the the most attractive opportunities for both near- and long-term value creation," concluded Mr. Meckler.

Financial Highlights for the Three and Twelve Months Ended December 31, 2018

Research and development expenses, net, for the three-month period ended December 31, 2018 were approximately $10.3 million, an increase of $1.4 million, or approximately 16%, compared with approximately $8.9 million in the three-month period ended December 31, 2017. Research and development expenses, net, for the year ended December 31, 2018 were approximately $35.4 million, an increase of $11.1 million, or approximately 46%, compared with approximately $24.3 million in the prior year period. The increase in both periods was primarily due to an increase in expenses related to the progression of our ACCORDANCE study and OLE study, expenses related to the establishment of the commercial scale production capabilities for AP-CD/LD at LTS, share-based compensation and payroll and related expenses, mostly due to an increase in headcount. This increase was offset by a decrease in expenses related to the repayment to the Israel Innovation Authority, which were recorded in 2017.

General and administrative expenses for the three-month period ended December 31, 2018 were approximately $2.1 million, an increase of $500,000, or approximately 31%, compared with approximately $1.6 million in the three-month period ended December 31, 2017. General and administrative expenses for the year ended December 31, 2018 were approximately $7.9 million, an increase of $2.8 million, or approximately 55%, compared with approximately $5.1 million in the year ended December 31, 2017. The increase in both periods was primarily related to the increase in share-based compensation and payroll and related expenses primarily related to the hiring of executives in the United States since the fourth quarter of 2017, professional services and expenses related to investor relations activities.

Net loss for the three-month period ended December 31, 2018 was approximately $12.6 million, an increase of $2.5 million, or approximately 25%, compared with the loss and comprehensive loss for the three-month period ended December 31, 2017 of approximately $10.2 million. Net loss for the fiscal year ended December 31, 2018 was approximately $43.5 million, an increase of $14.6 million, or approximately 51%, compared with the net loss for the same period ended December 31, 2017 of approximately $28.9 million. The increase in both periods was mainly due to an increase in research and development expenses and general and administrative expenses as detailed above.

Loss per ordinary share for the fourth quarter ended December 31, 2018 was $0.38 compared with $0.39 for the fourth quarter ended December 31, 2017. Loss per ordinary share for the full-year 2018 was $1.40 compared with $1.64 for the full-year 2017.

As of December 31, 2018, the Company had cash and cash equivalents and marketable securities of approximately $40.6 million compared with approximately $55.2 million at December 31, 2017.

Net cash used in operating activities was approximately $39.1 million for the year ended December 31, 2018 compared with net cash used in operating activities of approximately $22.1 million for the year ended December 31, 2017. This increase resulted from an increase in the Company's net loss of approximately $14.6 million and changes in operating asset and liability items of approximately $5.8 million which were offset by an increase in expenses not involving cash flows of approximately $3.4 million.

The Company had negative cash flow from investing activities of approximately $9.3 million for the year ended December 31, 2018 compared to negative cash flow from investing activities of approximately $4.7 million for the year ended December 31, 2017. This increase resulted primarily from investment in other assets related to production equipment in the amount of approximately $4.9 million offset by a decrease in purchase of property and equipment in the amount of approximately $334,000.

Net cash provided by financing activities was approximately $35.1 for the year ended December 31, 2018 compared with net cash provided by financing activities of approximately $63.7 million for the year ended December 31, 2017. The principal source of the cash provided by financing activities during 2018 was the funds received from the Company's April 2018 underwritten public offering of ordinary shares that resulted in net proceeds of approximately $35.0 million.

About Intec Pharma Ltd.

Intec Pharma is a clinical-stage biopharmaceutical company focused on developing drugs based on its proprietary Accordion Pill platform technology. The Company's Accordion Pill is an oral drug delivery system that is designed to improve the efficacy and safety of existing drugs and drugs in development by utilizing an efficient gastric retention and specific release mechanism. The Company's product pipeline includes two product candidates in clinical trial stages: Accordion Pill Carbidopa/Levodopa, or AP-CD/LD, which is in late-stage Phase 3 development for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, and AP-cannabinoids, an Accordion Pill to deliver either or both of the primary cannabinoids contained in Cannabis sativa, cannabidiol (CBD) and tetrahydrocannabinol (THC) for various pain indications.

For more information, visit www.intecpharma.com. We routinely post information that may be important to investors in the Investor Relations section of our website.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward looking statements about our expectations, beliefs and intentions. Forward-looking statements can be identified by the use of forward-looking words such as "believe", "expect", "intend", "plan", "may", "should", "could", "might", "seek", "target", "will", "project", "forecast", "continue" or "anticipate" or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. These forward-looking statements are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are outside of our control. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the following: our limited operating

history and history of operating losses, our ability to continue as a going concern, our ability to obtain additional financing, our ability to successfully operate our business or execute our business plan, the timing and cost of our clinical trials, the completion and receiving favorable results in our clinical trials, our ability to obtain and maintain regulatory approval of our product candidates, our ability to protect and maintain our intellectual property and licensing arrangements, our ability to develop, manufacture and commercialize our product candidates, the risk of product liability claims, the availability of reimbursement, and the influence of extensive and costly government regulation. More detailed information about the risks and uncertainties affecting us is contained under the heading "Risk Factors" included in our most recent Annual Report on Form 10-K to be filed with the SEC on February 27, 2019, and in other filings that we have made and may make with the Securities and Exchange Commission in the future.

-Tables to Follow-

INTEC PHARMA LTD.
CONSOLIDATED BALANCE SHEETS

	December 31	
	2018	**2017**
	U.S. dollars in thousands	
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 39,246	$ 53,393
Investment in marketable securities	1,333	1,825
Prepaid expenses and other receivables	2,986	1,125
TOTAL CURRENT ASSETS	43,565	56,343
NON-CURRENT ASSETS:		
Other assets	5,431	-
Property and equipment, net	12,233	8,206
Deferred tax assets	281	-
TOTAL NON-CURRENT ASSETS	17,945	8,206
TOTAL ASSETS	$ 61,510	$ 64,549
Liabilities and shareholders' equity		
CURRENT LIABILITIES -		
Accounts payable and accruals:		
Trade	$ 2,849	$ 1,854
Other	4,807	3,893
TOTAL CURRENT LIABILITIES	7,656	5,747
LONG-TERM LIABILITIES -		
Other liabilities	309	-
TOTAL LIABILITIES	7,965	5,747
COMMITMENTS AND CONTINGENT LIABILITIES		
SHAREHOLDERS' EQUITY:		
Ordinary shares, with no par value - authorized: 100,000,000 and 50,000,000 Ordinary Shares as of December 31, 2018 and December 31, 2017, respectively; issued and outstanding: 33,232,988 and 26,075,770 Ordinary Shares as of December 31, 2018 and December 31, 2017, respectively	727	727
Additional paid-in capital	194,642	156,356
Accumulated deficit	(141,824)	(98,281)
TOTAL SHAREHOLDERS' EQUITY	53,545	58,802
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 61,510	$ 64,549

INTEC PHARMA LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31	
	2018	**2017**

	U.S. dollars in thousands	
OPERATING EXPENSES:		
RESEARCH AND DEVELOPMENT EXPENSES, net	$ (35,402)	$ (24,295)
GENERAL AND ADMINISTRATIVE EXPENSES	(7,926)	(5,144)
OPERATING LOSS	(43,328)	(29,439)
FINANCIAL INCOME (EXPENSES), net	(112)	559
LOSS BEFORE INCOME TAX	(43,440)	(28,880)
INCOME TAX	(103)	(29)
NET LOSS	$ (43,543)	$ (28,909)
LOSS PER SHARE BASIC AND DILUTED	$ (1.40)	$ (1.64)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER ORDINARY SHARE IN THOUSANDS	31,193	17,660

INTEC PHARMA LTD.

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

	Ordinary Shares		Additional paid-in capital	Accumulated Deficit	Total
	Number of shares	Amounts	Amounts		
	U.S. dollars in thousands				
BALANCE AT JANUARY 1, 2017	11,448,191	$ 727	$ 91,446	$ (69,372)	$ 22,801
CHANGES DURING 2017:					
Issuance of ordinary shares, net of issuance costs	14,514,138	-	63,131	-	63,131
Exercise of warrants	102,058	-	531	-	531
Exercise of options by employees	11,383	-	45	-	45
Share-based compensation	-	-	1,203	-	1,203
Net loss	-	-	-	(28,909)	(28,909)
BALANCE AT DECEMBER 31, 2017	26,075,770	$ 727	$ 156,356	$ (98,281)	**$ 58,802**
CHANGES DURING 2018:					
Issuance of ordinary shares, net of issuance costs	7,150,000	-	35,029	-	35,029
Exercise of options by employees	7,218	-	30	-	30
Share-based compensation	-	-	3,227	-	3,227
Net loss	-	-	-	(43,543)	(43,543)
BALANCE AT DECEMBER 31, 2018	33,232,988	$ 727	$ 194,642	$ (141,824)	53,545

INTEC PHARMA LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31	
	2018	2017
	U.S. dollars in thousands	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (43,543)	$ (28,909)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	859	829
Exchange differences on cash and cash equivalents	829	(127)
Losses (gains) on marketable securities	194	(220)
Loss from sale of property and equipment	-	2
Share-based compensation	3,227	1,203
Changes in operating assets and liabilities:		
Decrease (increase) in prepaid expenses and other receivables	(1,861)	1,259
Increase in deferred tax assets	(281)	-
Increase in accounts payable and accruals	1,191	3,831
Increase in other liabilities	309	-

Net cash used in operating activities	(39,076)	(22,132)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(4,667)	(5,001)
Investment in other assets	(4,932)	-
Proceeds from disposal of marketable securities, net	298	247
Proceeds from sale of property and equipment	-	7
Net cash used in investing activities	(9,301)	(4,747)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of ordinary shares, net of issuance costs	35,029	63,131
Proceeds from exercise of warrants	-	531
Proceeds from exercise of options by employees	30	45
Net cash provided by financing activities	35,059	63,707
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(13,318)	36,828
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE YEAR	53,393	16,438
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(829)	127
CASH AND CASH EQUIVALENTS AT END OF THE YEAR	$ 39,246	$ 53,393
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING ACTIVITIES:		
Liability with respect to property and equipment	170	-
Liability with respect to other assets	499	-
SUPPLEMENTARY DISCLOSURE OF CASH FLOW INFORMATION:		
Taxes paid	96	-
Interest received	734	244

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